National Institute for Health and Care Excellence

Draft for consultation

Antenatal Care

[P] Fetal movement monitoring

NICE guideline tbc

Methods, evidence and recommendations Evidence reviews underpinning recommendations 1.2.31 to 1.2.32 and 1.3.9

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Draft for consultation

These evidence reviews were developed by the National Guideline Alliance which is a part of the Royal College of Obstetricians and Gynaecologists

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ISBN:

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Fetal movement monitoring

Review question

Is fetal movement monitoring from 28 weeks effective?

Introduction

All pregnant women are currently advised to monitor fetal movements in pregnancy and to contact their local unit if concerned, however there is uncertainty about whether formal approaches to raising awareness of and monitoring fetal movement lead to improvements in birth outcomes. This review aims to investigate the effectiveness of fetal movement monitoring on fetal wellbeing.

Summary of the protocol

See Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO table)

Population	All unselected low-risk pregnancies
Intervention	• Any fetal movement monitoring method, combination of methods, or regimen, for example: ○ Asking women to check for fetal movement ○ Asking women about fetal movement at every visit ○ Formal methods to assess fetal movement (such as Cardiff kick chart) Note: electronic fetal monitoring will not be considered in this review.
Comparison	• Any other fetal movement monitoring test, combination of tests or regimen • No intervention
Outcome	**Critical outcomes** • Maternal anxiety • Admission to neonatal unit • Perinatal mortality (stillbirth at or after 24+0 weeks' gestation and neonatal death up to 6 weeks after birth) **Important outcomes** • Gestational age at birth ○ Number of babies born at <37+0 weeks ○ Number of babies born at 37+1 to 38+6 weeks ○ Number of babies born at ≥39 weeks • Induction of labour • Length of neonatal stay in neonatal unit • Mode of birth ○ Vaginal birth - Spontaneous - Assisted ○ Caesarean section - Elective - Emergency

For further details, see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review question are described in the review protocol in appendix A.

Declarations of interest were recorded according to NICE's conflicts of interest policy.

Clinical evidence

Included studies

Five studies reporting 4 randomised controlled trials (RCTs) were included in this review. (Akselsson 2020, Grant 1989, Norman 2018 and Saastad 2011, with Saastad 2012 reporting on an additional outcome from the same study as Saastad 2011).

The included studies are summarised in Table 2.

Two studies compared fetal movement counting to standard care (Grant 1989, Saastad 2011). One study compared a programme called mindfetalness, which focused on having awareness of fetal movements, to standard care (Akselsson 2020). One study compared the implementation of an overall reduced fetal movement awareness package (aimed at pregnant women and their healthcare professionals) to standard care (Norman 2018).

One study was a multi-country study conducted in the UK, Belgium, Sweden, Ireland and US (Grant, 1989); 1 study was conducted in Norway (Saastad 2011); 1 study was conducted in Sweden (Akselsson 2020); 1 study was conducted in the UK and Ireland (Norman 2018).

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the evidence review

Summaries of the studies that were included in this review are presented in Table 2.

Table 2: Summary of included studies

Study	Population	Intervention	Comparison	Outcomes	Comments
Akselsson 2020 Cluster RCT Sweden	N=39865 pregnant women (67 clusters) Mean maternal age: Intervention: 32.1 years Control: 32.4 years	Mindfetalness: Women received a leaflet from midwives explaining how to practise mindfetalness, Women told to practise mindfetalness from 28 weeks onwards to birth. Mindfetalness involves laying on their side for 15 minutes daily while the fetus was	Usual care: The usual antenatal care provided in Sweden. Women were not informed about mindfetalness.	• Admission to neonatal unit • Perinatal mortality • Gestational age at birth • Induction of labour • Mode of birth; caesarean section	

Study	Population	Intervention	Comparison	Outcomes	Comments
		moving, and monitoring strength and frequency of movements. It does not involve counting the movements. Women told to trust their intuition when seeking care if they felt worried.			
Grant 1989 Cluster RCT UK, Belgium, Sweden, Ireland, US	N=68654 pregnant women (66 paired clusters) Mean maternal age: 26.5 years	Fetal movement counting. Women used the Cardiff 'count to ten' chart. They were taught by specially employed midwives on how to record movements. Women counted fetal movements every day and were instructed to contact the hospital if there was reduced movement. Reduced fetal movements was defined as no movements in one day, or less than 10 movements in 2 consecutive days. In Belgium, less than 10 movements in 1 day was considered. Clinicians were asked to respond to reduced movement reports as they thought best appropriate.	Women were not asked to count movements routinely, but could raise concerns or be asked about movements at antenatal visits. Obstetricians could give charts to select groups of women if circumstances dictated. Clinicians were asked to respond to reduced movement reports as they thought best appropriate.	• Maternal anxiety • Perinatal mortality	
Norman 2018 Stepped wedge, cluster RCT UK (England, Northern Ireland,	N=409175 pregnant women (33 clusters) Mean maternal age: Intervention: 30.3 Control: 30.0	Fetal movement awareness package: A web-based education package was provided to all clinical staff in the participating hospitals, explaining the importance of changes in	Usual care process in each study site. No further detail provided for specific sites.	• Admission to neonatal unit • Perinatal mortality • Gestational age at birth • Induction of labour • Mode of birth; spontaneous	

Study	Population	Intervention	Comparison	Outcomes	Comments
Scotland and Wales) and Ireland		frequency of fetal movements. Women were provided with a fetal movement leaflet. A management plan following reduced fetal movements included a cardiotocography, measurement of liquor volume and a growth scan. Use of an umbilical artery Doppler in addition to the growth scan was encouraged if available.		vaginal birth, elective caesarean, emergency caesarean	
Saastad 2011 RCT Norway	N=1076 pregnant women Maternal age ≥35 years: Intervention: 18% Control: 19.9%	Fetal movement counting. Women received an information brochure with instructions on how to use a fetal movement chart. They were asked to count using a modified count to 10 method. A midwife or obstetrician contacted the women within 2 weeks of the start to ensure correct interpretation of counting instructions.	Standard antenatal care in accordance with the Norwegian guideline. No further elaboration provided.	• Admission to neonatal unit • Perinatal mortality • Gestational age at birth • Induction of labour • Mode of birth; Spontaneous vaginal birth, elective caesarean, emergency caesarean	Additional outcome from same trial is reported in Saastad 2012.
Saastad 2012 RCT Norway	N=1013 pregnant women Mean maternal age: Intervention: 30.5 years Control: 30.2 years	See Saastad 2011.	See Saastad 2011.	• Maternal anxiety	Additional outcomes from same trial are reported in Saastad 2011.

RCT: randomised controlled trial.

See the full evidence tables in appendix D. No meta-analysis was conducted due to heterogeneity across the interventions (and so there are no forest plots in appendix E).

Quality assessment of studies included in the evidence review

See the evidence profiles in appendix F.

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no economic studies were identified which were applicable to this review question.

A single economic search was undertaken for all topics included in the scope of this guideline. See supplementary material 2 for details.

Excluded studies

Economic studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the economic evidence review

No economic studies were identified which were applicable to this review question.

Economic model

A bespoke economic analysis was undertaken to estimate the cost-effectiveness of formal fetal movement package in addition to usual care compared to no package. For the full economic report, see appendix J.

Overview of methods

The economic evaluation was conducted in the form of a cost-utility analysis (CUA), with outcomes expressed in terms of the cost per quality adjusted life year (QALY). The analysis was developed in Microsoft Excel and was conducted from the perspective of the NHS and Personal Social Services (PSS) as outlined in the NICE Reference Case (see Developing NICE guidelines: the manual).

The economic analysis was based on effectiveness data sourced from the clinical evidence review. The main analysis compared no formal awareness package (NFA) with an awareness package of formal fetal movement monitoring intervention (AFFIRM). The study informing the clinical model inputs (Norman 2018) was deemed highly applicable for informing the model as the study best reflected UK practice. Another intervention, 'Mindfetalness' was included in the analysis for this topic (Akselsson 2020). In the primary analysis to consider Mindfetalness separately to AFFIRM as the population, intervention and data pertaining to resource use was wholly different between them. A ranked comparison was also presented comparing all AFFIRM, Mindfetalness and NFA but this should be interpreted with caution. Baseline rates were derived from the relevant studies and from Norman 2018 for the ranked analysis

The clinical conditions considered were determined by the availability of relevant clinical data, as identified in the systematic review undertaken for this evidence topic. The following clinical outcomes were modelled:

- admission to neonatal intensive care units (NICU)
- perinatal mortality
- induction of labour
- spontaneous vaginal birth

- assisted vaginal birth
- elective caesarean section
- emergency caesarean section.

The model was structured as an incremental analysis, a hypothetical cohort of women was allocated to either formal awareness package or NFA with the costs and effects for each treatment strategy tracked. Owing to wider stakeholder and political interest in this topic, the model substituted perinatal mortality for stillbirth in a separate analysis to see if this had any bearing on the cost effectiveness interpretation. In addition, the associated costs and QALYs of the interventions themselves, and corresponding management strategies were also included in the model output.

Costs related to outcomes were, where possible, obtained from the National Schedule of NHS Costs (formerly NHS Reference Costs). Costs were based on a 2018/19 price year, reflecting the most recently available database at the time of writing. Costs related to stillbirth were extracted from a UK cost-of-illness study (Campbell 2018) which included a range of indirect NHS costs related to stillbirth. The costs associated with the management strategy for each intervention were itemised separately, and subsequently summed to provide a total cost of each intervention.

Quality adjusted life years (QALYs) were computed for: perinatal mortality; spontaneous vaginal birth; elective caesarean section and emergency caesarean section. EQ-5D utility data informing QALYs were informed from published sources (Kind 1999; Petrou 2017). In order to reflect the protocol of this evidence review, QALYs derived from the EQ-5D were also estimated for maternal anxiety associated with awareness packages and from stillbirth and neonatal mortality.

Main findings

The base case results compared NFA with AFFIRM. In the deterministic analysis, NFA was found to be less costly (-£182) and more effective (0.006 QALYs). The results of the PSA were in accordance with the deterministic analysis, with NFA being 82% likely to be the most cost effective approach when compared to AFFIRM at a cost effectiveness threshold of £20000 per QALY. In addition, the cost effectiveness interpretation held even at extreme values of various model inputs, as demonstrated in a series of one-way and two-way sensitivity analyses. When all 3 approaches were compared simultaneously NFA had a greater than 50% probability of being the most cost effective approach compared to the 2 formal awareness packages.

The main strengths of this economic analysis are that it provides economic evidence to a relevant policy making decision problem. To the best of our knowledge, no other economic evaluations have been conducted which consider the cost effectiveness of formal fetal monitoring awareness packages, despite the potentially considerable resource consequences entailed from such interventions. Also, the clinical evidence underpinning this analysis as well as much of the model inputs are in accordance with the NICE Reference Case. The driver of NFA being cost effective is that women who undergo NFA were less likely to experience an expedited birth which has extra associated costs and potential harms.

The main limitations of this analysis are that the model does not include outcomes and the costs and benefits related to morbidity. These were not included as there was insufficient clinical data obtained from the clinical review. The cost effectiveness interpretation may be altered once the potentially considerable disabilities and costs associated with such outcomes are factored in. That being said, the baseline event rates are likely to be reasonably low – it would likely require a considerable effectiveness estimate to have any impact on the overall model output.

Another limitation is the lack of resource data that may be associated with each treatment strategy. Owing to this, some assumptions had to be made, with input from the committee.

Nevertheless, as the cost effectiveness interpretation held under many scenario analyses, it is unlikely that more information would alter the model results.

Evidence statements

Clinical evidence statements

Comparison 1. Asking women to count fetal movements versus usual care

Critical outcomes

Maternal anxiety

- Moderate quality evidence from 1 RCT (N=1013) showed that there is no clinically important difference between asking women to count fetal movements and usual care on maternal anxiety measured by the Cambridge Worry Scale (range of score 0-5): mean difference (MD) -0.13 (95% CI -0.20 to -0.06).
- Low quality evidence from 1 RCT (N=68654, 66 paired clusters) showed that there is no clinically important difference between asking women to count fetal movements and usual care on maternal anxiety (rate of women reporting very/quite anxious per 100 women): MD 2 (95% CI -1.80 to 5.80).

Admission to neonatal unit

- Low quality evidence from 1 RCT (N=1076) showed that there is no clinically important difference between asking women to count fetal movements and usual care on admission to the neonatal unit: risk ratio (RR) 1.08 (95% CI 0.67 to 1.74).

Perinatal mortality

- High quality evidence from 1 RCT (N=1076) showed no statistically significant difference between asking women to count fetal movements and usual care on perinatal deaths (zero events in either arm): RD 0.00 (95% CI -0.00 to 0.00).
- Moderate quality evidence from 1 RCT (N=68654, 66 paired clusters) showed that there is no statistically significant difference between asking women to count fetal movements and usual care on perinatal death (rate of antepartum late fetal deaths per 1000 singleton births): MD 0.24 (95% CI -0.50 to 0.98) p=0.53.

Important outcomes

Gestational age at birth

- High quality evidence from 1 RCT (N=1076) showed that there is no clinically important difference between asking women to count fetal movements and usual care on gestational age at birth (days): MD 1 (95% CI -0.32 to 2.32).

Induction of labour

- Low quality evidence from 1 RCT (N=1076) showed that there is no clinically important difference between asking women to count fetal movements and usual care on induction of labour: RR 1.03 (95% CI 0.79 to 1.34).

Length of neonatal stay in neonatal unit

No evidence was identified to inform this outcome.

Mode of birth

- High quality evidence from 1 RCT (N=1076) showed that there is no clinically important difference between asking women to count fetal movements and usual care on spontaneous vaginal birth: RR 1.01 (95% CI 0.95 to 1.07).
- Low quality evidence from 1 RCT (N=1076) showed that there is no clinically important difference between asking women to count fetal movements and usual care on elective caesarean sections: RR 0.83 (95% CI 0.52 to 1.35).
- Low quality evidence from 1 RCT (N=1076) showed that there is no clinically important difference between asking women to count fetal movements and usual care on emergency caesarean sections: RR 1.72 (95% CI 0.51 to 5.85).

Comparison 2. AFFIRM package versus usual care

Critical outcomes

Maternal anxiety

No evidence was identified to inform this outcome.

Admission to neonatal unit

- High quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on admission to neonatal unit: odds ratio (OR) 1.02 (95% CI 0.97 to 1.07).

Perinatal mortality

- High quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no statistically significant difference between receiving the AFFIRM package and usual care on perinatal death: OR 0.98 (95% CI 0.83 to 1.16) p=0.81.

Important outcomes

Gestational age at birth

- Low quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on estimated gestation <37+0 weeks: RR 1.1 (95% CI 0.74 to 1.64).
- Moderate quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on estimated gestation >37 weeks to ≤39 weeks: RR 1.05 (95% CI 0.86 to 1.29).
- High quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on estimated gestation >39 weeks: RR 0.96 (95% CI 0.81 to 1.14).

Induction of labour

- High quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on induction of labour: OR 1.05 (95% CI 1.02 to 1.08).

Length of neonatal stay in neonatal unit

No evidence was identified to inform this outcome.

Mode of birth

- High quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on spontaneous vaginal birth: OR 0.90 (95% CI 0.88 to 0.92).

- Low quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on elective caesarean section: RR 1.13 (95% CI 0.74 to 1.73).
- Low quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on emergency caesarean section: RR 1.09 (95% CI 0.73 to 1.61).
- High quality evidence from 1 RCT (N=409175, 33 clusters) showed that there is no clinically important difference between receiving the AFFIRM package and usual care on caesarean section (overall): OR 1.09 (95% CI 1.06 to 1.12).

Comparison 3. Mindfetalness versus usual care

Critical outcomes

Maternal anxiety

No evidence was identified to inform this outcome.

Admission to neonatal intensive care unit

- High quality evidence from 1 RCT (N=39865, 67 clusters) showed that there is no clinically important difference between receiving mindfetalness and usual care on admission to neonatal intensive care unit: RR 0.93 (95% CI 0.86 to 1.00).

Perinatal mortality

- Low quality evidence from 1 RCT (N=39865, 67 clusters) showed that there is no statistically significant difference between receiving mindfetalness and usual care on neonatal mortality (death within 27 days of birth): RR 0.41 (95% CI 0.06 to 1.19) p=0.27.
- Low quality evidence from 1 RCT (N=39865, 67 clusters) showed that there is no statistically significant difference between receiving mindfetalness and usual care on perinatal mortality (composite outcome of neonatal mortality and stillbirths): Peto OR 1.03 (95% CI 0.06 to 16.49) p=0.98.

Important outcomes

Gestational age at birth

- High quality evidence from 1 RCT (N=39865, 67 clusters) showed that there is no clinically important difference between receiving mindfetalness and usual care on gestational age at birth <37+0 weeks: RR 1.01 (95% CI 0.91 to 1.12).
- High quality evidence from 1 RCT (N=39865, 67 clusters) showed that there is no clinically important difference between receiving mindfetalness and usual care on gestational age at birth >41+6 weeks: RR 0.91 (95% CI 0.83 to 0.98).

Induction of labour

- High quality evidence from 1 RCT (N=39865, 67 clusters) showed that there is no clinically important difference between receiving mindfetalness and usual care on induction of labour: RR 0.96 (95% CI 0.92 to 1.00).

Length of neonatal stay in neonatal unit

No evidence was identified to inform this outcome.

Mode of birth

- High quality evidence from 1 RCT (N=39865, 67 clusters) showed that there is no clinically important difference between receiving mindfetalness and usual care on caesarean section: RR 0.95 (95% CI 0.91 to 0.99).

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

Current practice advises women to monitor their fetal movements. It is not clear whether monitoring fetal movements has benefits to the fetus or whether it might cause harm to the mother (for example by encouraging unnecessary interventions by healthcare professionals or undue anxiety). The committee therefore agreed that maternal anxiety, admission to neonatal unit and perinatal mortality, were critical outcomes. The committee wanted to determine whether monitoring fetal movements will increase use of intervention at birth or whether it affects the time of birth, therefore gestational age at birth, induction of labour, length of stay in neonatal unit and mode of birth were considered important outcomes.

The quality of the evidence

The quality of the evidence for establishing whether fetal movement monitoring is effective from 28 weeks ranged from low to high, with most of the evidence of high quality. The main issues were due to imprecision around the estimate of effects in many outcomes. Some outcomes (for example maternal anxiety) were also downgraded for risk of bias as they were subjective and from non-blinded trials.

Maternal anxiety was identified as a critical outcome. It was reported in two studies that compared asking women to count fetal movements to usual care. Maternal anxiety was not reported for the AFFIRM package versus usual care comparison, or for the mindfetalness versus usual care comparison.

The committee agreed that it was important to note that in the trial that compared the AFFIRM package to usual care, there were problems with adherence. Approximately 40% of centres adhered to 4 or less of the 5 components of the AFFIRM package. The components included:

- Implementation of the e-learning education package for staff
- Issue of reduced fetal movement leaflet to pregnant women
- Implementation of any of the 3 aspects of the management plan:
  1) Perform a cardiotocography
  2) Measure liquor volume
  3) Perform a growth scan and if available, an umbilical artery Doppler.

No evidence was identified for the outcome length of stay in the neonatal unit.

Benefits and harms

There were 2 studies (reported in 3 publications) that compared asking women to count fetal movements with usual care. The evidence showed that asking women to count fetal movements did not have clinically important benefits or harms for any of the outcomes.

One study (AFFIRM) compared a fetal movement awareness package given to mothers and clinicians with usual care. The evidence showed that this awareness package did not have any benefits or harms of a magnitude to be considered clinically important by default on any of the outcomes of interest. Importantly, high quality evidence showed that the awareness package did not have an impact on perinatal mortality which was the main driver in the committee's conclusions of the evidence. However, high quality evidence showed small but statistically significant differences in overall caesarean section, induction of labour (both increased with the awareness package) and spontaneous vaginal birth (decreased with the awareness package) and these were also considered when making recommendations. The study did not report maternal anxiety but the committee agreed it was possible that maternal

anxiety may be increased by an awareness package that emphasises the risks of reduced fetal movements. These possible harms must be balanced against the primary intention of the package which is to reduce neonatal morbidity and mortality. The evidence in this review showed that there was no important difference for any of these outcomes, suggesting the package was leading to more interventions without creating definitive benefit.

One study compared mindfetalness, an intervention that uses a leaflet to teach women a method of being aware of fetal movements without counting them, to usual care. The evidence showed that mindfetalness did not have clinically important benefits or harms to any of the outcomes of interest. However, there were a number of small but statistically significant differences in some outcomes, showing tendency to favour mindfetalness when compared with usual care. Mindfetalness had borderline fewer admissions to neonatal intensive care unit and inductions of labour than usual care. There were also statistically significantly fewer births at gestational age greater than 41+6 weeks and fewer caesarean sections with mindfetalness.

Overall the committee agreed it was important that the results of this evidence did not stop healthcare professionals inquiring about and responding in a timely manner to women's concerns around reductions in fetal movement after 24+0 weeks of gestation. The committee also recognised the importance of ensuring women are listened to and therefore recommended advising women that maternity services are available 24 hours should they wish to raise any concerns or if they observe reduced fetal movements. The committee made a recommendation in line with current practice, that when there are concerns about fetal movements, the woman and the baby should be assessed. However, the committee agreed that a formal awareness package put in place across healthcare settings as done in the AFFIRM trial did not have a benefit, was associated with possible harms and was not cost effective. Therefore, the committee felt it was important to make a recommendation to highlight that the evidence does not support the specific awareness package used in the trial. The high quality of the evidence, and the large sample size of the trial supported the committee's decision. As noted above the committee highlighted the issues of adherence in the AFFIRM trial, while this may be expected to limit the potential benefit of the intervention, the committee agreed this did not prevent them from making a recommendation about its efficacy. There is no reason to expect that adherence to the package is likely to be any better outside of a trial context and in fact it is generally considered that adherence to complex interventions is greater in the context of clinical trials.

The committee discussed the 'mindfetalness' package used in the other trial and agreed that the intervention was not a reflection of current practice in the UK as the intervention in the AFFIRM trial is. They agreed that the evidence around this intervention's possible benefits and harms was not strong enough, or relevant enough to UK practice to warrant a specific recommendation, although the recommendations made by the committee did capture the concept of encouraging women to seek care if they felt worried.

Cost effectiveness and resource use

A systematic review of the economic literature was conducted but no relevant studies were identified which were applicable to this review question.

Structured fetal movement awareness package, encouraged by the implementation of the care bundle is now standard practice in nearly all NHS trusts. However, there has been limited evidence guiding this recommendation with roll out occurring before the results of the AFFIRM trial (Norman 2018) were published. This study, included in the accompanying clinical review informed all of the main clinical outcomes in the guideline economic analysis and was believed by the committee to be highly relevant to UK practice.

The structured fetal movement awareness packages are associated with increased overall caesarean section rates and fewer spontaneous births. The associated differences in costs and QALYs resulting from the different proportions of women experiencing these outcomes

between the structured fetal movement awareness package and no formal package was a key driver of cost effectiveness in the model. Results from the economic model showed that not formally promoting a structured fetal movement awareness package was both cost saving and health improving. Therefore, promoting a structured fetal movement awareness package for pregnant women to follow during pregnancy was not cost effective and not an efficient use of NHS resources.

The committee noted that the accompanying clinical evidence review did not identify evidence of effectiveness for a structured fetal movement awareness package on any of the outcomes considered in the protocol and the bespoke economic analysis strongly suggested such packages were not cost effective for a threshold of £20,000 per additional QALY. The committee highlighted that reducing perinatal mortality is a priority for the NHS. The NHS Saving Babies' Lives Care Bundle 2 is designed to provide guidance to commissioners and healthcare professionals to take action to reduce stillbirth and neonatal death. One element of the bundle is for health professionals to raise awareness of reduced fetal movement to pregnant women. Therefore, the committee were mindful of the importance of this topic and formed a recommendation raising awareness of the lack of evidence of effectiveness for such packages but not explicitly recommending against them.

References

Akselsson 2020

Akselsson, A., Lindgren, H., Georgsson, S., Pettersson, K., Steineck, G., Skokic, V., & Rådestad, I. Mindfetalness to increase women's awareness of fetal movements and pregnancy outcomes: a cluster-randomised controlled trial including 39 865 women. BJOG, 127, 829-837, 2020

Campbell 2018

Campbell, H. E., Kurinczuk, J. J., Heazell, A. E. P., Leal, J., & Rivero-Arias, O. Healthcare and wider societal implications of stillbirth: a population-based cost-of-illness study. BJOG: An International Journal of Obstetrics & Gynaecology, 125, 108-117, 2018

Grant 1989

Grant, A., Elbourne, D., Valentin, L., Alexander, S. Routine formal fetal movement counting and risk of antepartum late death in normally formed singletons, Lancet, 12, 345-9, 1989

Kind 1999

Kind, P., Hardman, G., Macran, S. UK Population norms for EQ-5D. Discussion paper 172. York: Centre for Health Economics, The University of York, 1999

Norman 2018

Norman, JE., Heazell, AEP., Rodriguez, A., Weir, CJ., Stock, SJE., Calderwood, CJ., Cunningham Burley, S., Frøen, JF., Geary, M., Breathnach, F., Hunter, A., McAuliffe, FM., Higgins, MF., Murdoch, E., Ross-Davie, M., Scott, J., Whyte, S., AFFIRM investigators. Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial, Lancet, 392,1629-1638, 2018

Petrou 2017

Petrou, S., Kim, S. W., McParland, P., & Boyle, E. M. Mode of delivery and long-term health-related quality-of-life outcomes: a prospective population-based study. Birth, 44, 110-119, 2017

Saastad 2011

Saastad, E., Winje, B. A., Stray Pedersen, B., Froen, J. F. Fetal movement counting improved identification of fetal growth restriction and perinatal outcomes--a multi-centre, randomized, controlled trial, PLoS ONE, 6, e28482, 2011

Saastad 2012

Saastad, E., Winje, B. A., Israel, P., Froen, J. F. Fetal movement counting--maternal concern and experiences: a multicenter, randomized, controlled trial, Birth, 39, 10-20, 2012

Appendices

Appendix A – Review protocol

Review protocol for review question: Is fetal movement monitoring from 28 weeks effective?

Table 3: Review protocol

Field	Content
Review question	Is fetal movement monitoring from 28 weeks effective?
Type of review question	Intervention review
Objective of the review	The aim of this review is to assess the effectiveness of fetal movement monitoring for fetal wellbeing during pregnancy.
Eligibility criteria – population	All unselected low-risk pregnancies.
Eligibility criteria – Intervention(s)	• Any fetal movement monitoring method, combination of methods, or regimen. For example: ○ Asking women to check for fetal movement ○ Asking women about fetal movement at every visit ○ Formal methods to assess fetal movement (such as Cardiff kick chart) Note: electronic fetal monitoring will not be considered in this review.
Eligibility criteria –Comparator(s)	• Any other fetal movement monitoring test, combination of tests or regimen No intervention
Outcomes and prioritisation	**Critical outcome** • Maternal anxiety • Admission to neonatal unit • Perinatal mortality (stillbirth at or after 24+0 weeks gestation and neonatal death up to 6 weeks after birth) **Important outcomes** • Gestational age at birth ○ Number of babies born at <37+0 weeks ○ Number of babies born at 37+1 to 38+6 weeks ○ Number of babies born at ≥39 weeks • Induction of labour • Length of neonatal stay in neonatal unit • Mode of birth ○ Vaginal birth - Spontaneous - Assisted ○ Caesarean section - Elective

Field	Content
	- Emergency
Eligibility criteria – study design	INCLUDE: For intervention review • Systematic reviews of randomised controlled trials • Randomised controlled trials (individual or cluster) Note: For further details, see the algorithm in appendix H, Developing NICE guidelines: the manual.
Other inclusion exclusion criteria	**Exclusion** POPULATION: • Studies exclusively on multiple pregnancies • Pregnancy with known or pre-existing congenital anomalies STUDY DESIGN: • Cohort studies • Case control studies • Cross-sectional studies • Epidemiological reviews or reviews on associations • Non-comparative studies PUBLICATION STATUS: • Conference abstract LANGUAGE: • Non-English **Inclusion** COUNTRY: High-income (as defined by the World Bank) countries only (see https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups for classification of countries**)**.
Proposed sensitivity/sub-group analysis, or meta-regression	Statistical heterogeneity will be assessed by visually examining the forest plots and by calculating the I^2 inconsistency statistic (with an I^2 value≥50% indicating serious heterogeneity, and ≥80% indicating very serious heterogeneity).
Selection process – duplicate screening/selection/analysis	Studies included in the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62) that satisfy the review protocol will be included in this review. Review questions selected as high priorities for health economic analysis (and those selected as medium priorities and where health economic analysis could influence recommendations) will be subject to dual weeding and study selection; any discrepancies above 10% of the dual weeded resources will be resolved through discussion between the first and second reviewers or by reference to a third person. All data extraction will quality assured by a senior reviewer. Draft excluded studies and evidence tables will be circulated to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.
Data management (software)	NGA STAR software will be used to generate bibliographies/citations, and perform conduct sifting and data extraction. Pairwise meta-analyses, if possible, will be conducted using Cochrane Review Manager (RevMan5). For details please see Supplement 1: methods. 'GRADEpro' will be used to assess the quality of evidence for each outcome.
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase. Limits (date, study design): • Date limit: 2006 (date of last search for the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62) • Apply standard animal/non-English language exclusion Limit to RCTs and systematic reviews in first instance but download all results.

Field	Content
Identify if an update	This antenatal care update will replace the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62), which will be taken down in due course. The following relevant recommendations in the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62) regarding fetal growth and well-being were made: 1.10.1 Symphysis–fundal height should be measured and recorded at each antenatal appointment from 24 weeks. [2008] 1.10.2 Ultrasound estimation of fetal size for suspected large-for-gestational-age unborn babies should not be undertaken in a low-risk population. [2008] 1.10.3 Routine Doppler ultrasound should not be used in low-risk pregnancies. [2008] 1.10.4 Fetal presentation should be assessed by abdominal palpation at 36 weeks or later, when presentation is likely to influence the plans for the birth. Routine assessment of presentation by abdominal palpation should not be offered before 36 weeks because it is not always accurate and may be uncomfortable. 1.10.5 Suspected fetal malpresentation should be confirmed by an ultrasound assessment. 1.10.6 Routine formal fetal-movement counting should not be offered. 1.10.7 Auscultation of the fetal heart may confirm that the fetus is alive but is unlikely to have any predictive value and routine listening is therefore not recommended. However, when requested by the mother, auscultation of the fetal heart may provide reassurance. 1.10.8 The evidence does not support the routine use of antenatal electronic fetal heart rate monitoring (cardiotocography) for fetal assessment in women with an uncomplicated pregnancy and therefore it should not be offered. 1.10.9 The evidence does not support the routine use of ultrasound scanning after 24 weeks of gestation and therefore it should not be offered.
Author contacts	Developer: National Guideline Alliance.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual.
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Quality assessment of individual studies will be performed using the following checklists: • ROBIS tool for systematic reviews • Cochrane RoB tool, v.2, for randomised controlled trials For details please see section 6.2 of Developing NICE guidelines: the manual. The risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual.
Methods for analysis – combining studies and exploring (in)consistency	For details please see Supplement 1: methods.
Meta-bias assessment – publication bias, selective reporting bias	For details please see Supplement 1: methods and section 6.2 of Developing NICE guidelines: the manual. If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual.
Rationale/context – Current management	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Kate Harding in line with section 3 of Developing NICE guidelines: the manual. Staff from the National Guideline Alliance undertook systematic literature

Field	Content
	searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see Supplement 1: methods.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	This protocol is not registered with PROSPERO.

CDSR: Cochrane Database of Systematic Reviews; CCTR: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; RCT: randomised controlled trial; RoB: risk of bias;

Appendix B – Literature search strategies

Literature search strategies for review question: Is fetal movement monitoring from 28 weeks effective?

Database(s): Medline & Embase (Multifile)
Last searched on **Embase Classic+Embase** 1947 to 2020 September 08, **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily** 1946 to September 08, 2020
Date of last search: 9th September 2020
Multifile database codes: emczd = Embase Classic+Embase; ppez= MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily

#	Searches
1	Pregnancy/ or Pregnancy Trimester, Third/ or *Prenatal Care/
2	pregnancy/ or third trimester pregnancy/ or *prenatal care/
3	pregnan$.tw,kw.
4	fetal well being/ use emczd
5	((fetal or foetal or fetus or foetus) adj (wellbeing$ or well-being$ or well being$)).tw,kw.
6	(1 or 3 or 5) use ppez
7	(2 or 3 or 5) use emczd
8	4 or 6 or 7
9	*Fetal Movement/ use ppez
10	*fetus movement/ use emczd
11	((fetal or foetal or fetus or foetus) adj movement$ adj2 (count$ or monitor$ or chart$ or rate$)).tw,kw.
12	((count$ or monitor$) adj2 (fetal or foetal or fetus or foetus) adj movement$).tw,kw.
13	((routine or formal) adj2 count$).tw,kw.
14	count$ chart$.tw,kw.
15	(FM adj (monitor$ or count$)).tw,kw.
16	((fetal or foetal or fetus or foetus) adj movement$ adj record$).tw,kw.
17	(record$ adj2 (fetal or foetal or fetus or foetus) adj movement$).tw,kw.
18	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19	Fetal Monitoring/ use ppez
20	fetus monitoring/ use emczd
21	19 or 20
22	((fetal or foetal or fetus or foetus) adj movement$).tw,kw.
23	21 and 22
24	((count$ or monitor$) adj3 movement$).tw,kw.
25	22 and 24
26	18 or 23 or 25
27	8 and 26
28	((fetal or foetal or fetus or foetus) adj movement$).m_titl.
29	27 or 28
30	(controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt. or drug therapy.fs. or (groups or placebo or randomi#ed or randomly or trial).ab.
31	crossover procedure/ or double blind procedure/ or randomized controlled trial/ or single blind procedure/ or (assign* or allocat* or crossover* or cross over* or ((doubl* or singl*) adj blind*) or factorial* or placebo* or random* or volunteer*).ti,ab.
32	meta-analysis/
33	meta-analysis as topic/
34	systematic review/
35	meta-analysis/
36	(meta analy* or metanaly* or metaanaly*).ti,ab.
37	((systematic or evidence) adj2 (review* or overview*)).ti,ab.
38	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
39	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
40	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
41	(search* adj4 literature).ab.
42	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
43	cochrane.jw.
44	((pool* or combined) adj2 (data or trials or studies or results)).ab.
45	letter/
46	editorial/
47	news/

#	Searches
48	exp historical article/
49	Anecdotes as Topic/
50	comment/
51	case report/
52	(letter or comment*).ti.
53	45 or 46 or 47 or 48 or 49 or 50 or 51 or 52
54	randomized controlled trial/ or random*.ti,ab.
55	53 not 54
56	animals/ not humans/
57	exp Animals, Laboratory/
58	exp Animal Experimentation/
59	exp Models, Animal/
60	exp Rodentia/
61	(rat or rats or mouse or mice).ti.
62	55 or 56 or 57 or 58 or 59 or 60 or 61
63	letter.pt. or letter/
64	note.pt.
65	editorial.pt.
66	case report/ or case study/
67	(letter or comment*).ti.
68	63 or 64 or 65 or 66 or 67
69	randomized controlled trial/ or random*.ti,ab.
70	68 not 69
71	animal/ not human/
72	nonhuman/
73	exp Animal Experiment/
74	exp Experimental Animal/
75	animal model/
76	exp Rodent/
77	(rat or rats or mouse or mice).ti.
78	70 or 71 or 72 or 73 or 74 or 75 or 76 or 77
79	62 use ppez
80	78 use emczd
81	79 or 80
82	30 use ppez
83	31 use emczd
84	82 or 83
85	(or/32-33,36,38-43) use ppez
86	(or/34-37,39-44) use emczd
87	85 or 86
88	29 and 81
89	29 not 88
90	limit 89 to english language
91	limit 90 to yr="2006 -Current"
92	84 or 87
93	91 and 92 [RCT/SR data]
94	91 not 93 [Non-RCT/SR data]

Database(s): Cochrane Library

Last searched on **Cochrane Database of Systematic Reviews**, Issue 9 of 12, September 2020, **Cochrane Central Register of Controlled Trials**, Issue 9 of 12, September 2020

Date of last search: 9th September 2020

#	Searches
#1	MeSH descriptor: [Pregnancy] this term only
#2	MeSH descriptor: [Pregnancy Trimester, Third] this term only
#3	MeSH descriptor: [Prenatal Care] this term only
#4	(pregnan*):ti,ab,kw
#5	(((fetal or foetal or fetus or foetus) NEAR/1 (wellbeing* or well-being* or "well being*"))):ti,ab,kw
#6	#1 OR #2 OR #3 OR #4 OR #5
#7	MeSH descriptor: [Fetal Movement] this term only
#8	(((fetal or foetal or fetus or foetus) NEAR/1 movement$ NEAR/2 (count* or monitor* or chart* or rate*))):ti,ab,kw
#9	(((count* or monitor*) NEAR/2 (fetal or foetal or fetus or foetus) NEAR/1 movement*)):ti,ab,kw
#10	(((routine or formal) NEAR/2 count*)):ti,ab,kw
#11	("count* chart*"):ti,ab,kw
#12	((FM NEAR/1 (monitor* or count*))):ti,ab,kw
#13	(((fetal or foetal or fetus or foetus) NEAR/1 movement* NEAR/1 record*)):ti,ab,kw
#14	((record* NEAR/2 (fetal or foetal or fetus or foetus) NEAR/1 movement*)):ti,ab,kw

#	Searches
#15	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14
#16	MeSH descriptor: [Fetal Monitoring] this term only
#17	(((fetal or foetal or fetus or foetus) NEAR/1 movement*)):ti,ab,kw
#18	#16 AND #17
#19	(((count* or monitor*) NEAR/3 movement*)):ti,ab,kw
#20	#17 AND #19
#21	#15 OR #18 OR #20
#22	#6 AND #21
#23	(((fetal or foetal or fetus or foetus) NEAR/1 movement*)):ti
#24	#22 OR #23 Publication Year from 2006 to current

Database(s): CRD: Database of Abstracts of Reviews of Effects (DARE), HTA Database

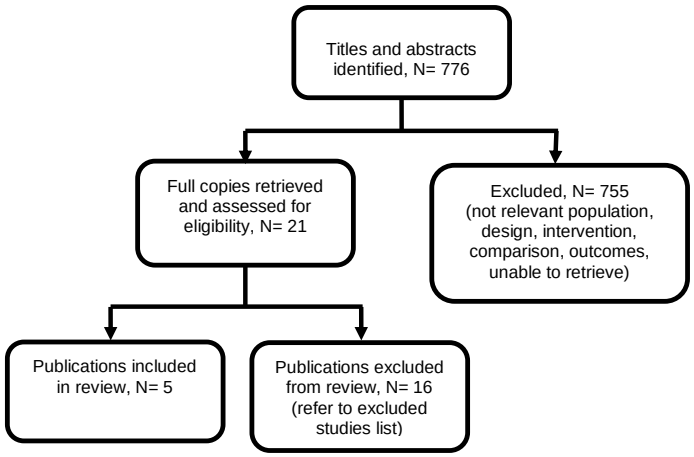
Date of last search: 9th September 2020

#	Searches
1	MeSH DESCRIPTOR pregnancy IN DARE,HTA
2	MeSH DESCRIPTOR Pregnancy Trimester, Third IN DARE,HTA
3	MeSH DESCRIPTOR prenatal care IN DARE,HTA
4	(pregnan*) IN DARE, HTA
5	(((fetal or foetal or fetus or foetus) NEAR1 (wellbeing* or well-being* or well being*))) IN DARE, HTA
6	#1 OR #2 OR #3 OR #4 OR #5
7	MeSH DESCRIPTOR Fetal Movement IN DARE,HTA
8	(((fetal or foetal or fetus or foetus) NEAR1 movement* NEAR2 (count* or monitor* or chart* or rate*))) IN DARE, HTA
9	(((count* or monitor*) NEAR2 (fetal or foetal or fetus or foetus) NEAR1 movement*)) IN DARE, HTA
10	(((routine or formal) NEAR2 count*)) IN DARE, HTA
11	(count* chart*) IN DARE, HTA
12	((FM NEAR1 (monitor* or count*))) IN DARE, HTA
13	(((fetal or foetal or fetus or foetus) NEAR1 movement* NEAR1 record*)) IN DARE, HTA
14	((record* NEAR2 (fetal or foetal or fetus or foetus) NEAR1 movement*)) IN DARE, HTA
15	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14
16	MeSH DESCRIPTOR Fetal Monitoring IN DARE,HTA
17	(((fetal or foetal or fetus or foetus) NEAR1 movement*)) IN DARE, HTA
18	#16 AND #17
19	(((count* or monitor*) NEAR3 movement*)) IN DARE, HTA
20	#17 AND #19
21	#15 OR #18 OR #20
22	#6 AND #21
23	(((fetal or foetal or fetus or foetus) NEAR1 movement*)):TI IN DARE, HTA
24	#22 OR #23 Publication Year from 2006 to current

Appendix C – Clinical evidence study selection

Study selection for: Is fetal movement monitoring from 28 weeks effective?

Figure 1: Study selection flow chart



1 Appendix D – Clinical evidence tables

2 Table 4: Evidence tables for review question: Is fetal movement monitoring from 28 weeks effective?

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
Full citation Akselsson, A., Lindgren, H., Georgsson, S., Pettersson, K., Steineck, G., Skokic, V., Radestad, I., Mindfetalness to increase women's awareness of fetal movements and pregnancy outcomes: a cluster-randomised controlled trial including 39 865 women, BJOG: An International Journal of Obstetrics & Gynaecology, 2020 **Ref Id** 1241702 **Country/ies where the study was carried out** Sweden **Study type** Cluster randomised controlled trial **Aim of the study**	**Sample size** Clusters: n=67 Intervention: n=19639 Control: n=20226 **Characteristics** Mean maternal age - years: Intervention: 32.1 Control: 32.4 Primiparous- number of women (%): Intervention: 8544 (43.5) Control: 8927 (44.1) **Inclusion criteria** Pregnant women with at least 25 weeks gestational age. Have a personal Swedish identity number. **Exclusion criteria** Maternity centres where less than 50	**Interventions** Mindfetalness: Midwives handed out leaflets to pregnant women at the 24 week gestational routine visit. Leaflet explained how to do 'mindfetalness'. Women told to start mindfetalness from 28 weeks gestation until birth. Mindfetalness involves laying down on the side for 15 minutes a day when the baby is awake and moving, and monitoring the strength and frequency of movements. Mindfetalness does not involve counting the movements. Women told to trust their intuition about seeking care if they felt worried. Control:	**Details** Power analysis: The outcome Apgar score of 0-6 at 5 minutes after birth was used to calculate the power of the study. 38655 women in a 16 month period required to give a 84% power to detect a decrease of 0.3% and 98% power to detect a decrease of 0.4%, at 5% level of significance. Statistical analysis: Intention to treat analysis. Relative risks calculated. To deal with issues arising from cluster randomisation, a large number of confounding factors were adjusted for.	**Results** Critical outcomes: <u>Admission to neonatal intensive care unit</u> - number (%): Intervention: 1242 (6.3) Control: 1377 (6.8) RR (95% CI): 0.93 (0.86–1.00) p=0.05 <u>Perinatal mortality:</u> Death within 27 days after birth - number (%): Intervention: 2 (0) Control: 5 RR (95% CI): 0.41 (0.06–1.91) p=0.27 Still birth – number (%): Intervention: 33 (0.2) Control: 29 (0.14), design effect adjustment carried out by NGA team for further analysis Important outcomes:	**Limitations** Cochrane risk of bias tool V2: Randomisation process: Low risk of bias. (Allocation random and carried out by non-researchers). Deviations from intended interventions: Low risk of bias. (Participants were not blinded, but unlikely to have an effect due to the nature of the intervention). Missing outcome data: Low risk of bias. (100% follow up). Measurement of the outcome: Low risk of bias. (Outcome assessors were blind to the intervention). Selection of the reported result: Low risk of bias. (Outcomes reported in the protocol were measured).

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
To find out whether mindfetalness has an effect on pregnancy outcomes **Study dates** November 2016 to January 2018 **Source of funding** Not industry funded	women registered annually. Specialised maternity clinics.	Women carried on with routine antenatal care. Women in the control arm were not told about the mindfetalness activities. No further details provided		<u>Gestational age at birth</u>: Number of babies born <37+0 weeks (%): Intervention: 700 (3.6) Control: 716 (3.5) RR (95% CI): 1.01 (0.91–1.12) p=0.9 Number of babies born 41+6 weeks (%): Intervention: 1015 (5.2) Control: 1154 (5.7) RR (95% CI): 0.91 (0.83–0.98) p=0.02 <u>Induction of labour</u> - number (%): Intervention: 3747 (19.1) Control: 4010 (19.8) RR (95% CI): 0.96 (0.92–1.00) p=0.06 <u>Mode of birth: caesarean section</u> (total) - number (%): Intervention: 3741 (19.0) Control: 4048 (20.0) RR (95% CI): 0.95 (0.91–0.99) p=0.02 Design effect adjustment carried out by authors for outcomes: admission to	Overall risk of bias: Low risk **Other information:** Compliance to the intervention was not monitored. 25% of women allocated to the intervention arm did not receive the mindfetalness leaflet.

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
				neonatal intensive care unit; death within 27 days after birth; gestational age at birth; induction of labour; caesarean section. Design effect adjustment carried out by NGA team for perinatal mortality outcome where deaths within 27 days after birth and stillbirths were combined. Where sample sizes required adjusting for cluster design by the NGA team, an assumed intracluster correlation coefficient (ICC) and the average cluster size were used. ICC=0.05 Average cluster size: 595 Adjusted sample size = sample size / design effect. Design effect = 1 + (average cluster size – 1) x ICC	
Full citation Grant, A., Elbourne, D., Valentin, L., Alexander, S., Routine formal fetal movement counting and risk of	**Sample size** N=68654 (66 paired clusters) Intervention: 31993 Control: 36661 **Characteristics**	**Interventions** Fetal movement counting: Women used the Cardiff 'count to ten'	**Details** Power analysis Total sample of 60000 women required for an 80% chance of detecting a reduction	**Results** Critical outcomes: <u>Maternal anxiety</u> Feeling very or quite anxious:	**Limitations** Cochrane risk of bias tool V2: Randomisation process: Unclear risk of bias. (Not enough information).

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
antepartum late death in normally formed singletons, Lancet (London, England), 2, 345-9, 1989 **Ref Id** 1119522 **Country/ies where the study was carried out** UK, Belgium, Sweden, Ireland, USA **Study type** Cluster randomised controlled trial **Aim of the study** To test if routine formal counting, and subsequent appropriate actions, reduces the rate of antepartum late death, and to examine what effects routine formal counting had on women and perinatal services. Study dates 1986 – 21 months later Source of funding Government and academia	Maternal age: mean 26.5 [SE 0-2] years Primiparity: 44.2 [0.9] versus 44.6 [0-9] Multiple pregnancies: mean 1.1 [0.1]. **Inclusion criteria** Gestational age between 28-32 weeks. **Exclusion criteria**	chart. They were taught by specially employed midwives on how to record movements. Women counted fetal movements every day and were instructed to contact the hospital if there was reduced movement. Reduced fetal movements was defined as no movements in one day, or less than 10 movements in 2 consecutive days. In Belgium, less than 10 movements in 1 day was considered. Clinicians were asked to respond to reduced movement reports as they thought best appropriate. Control: Women were not asked to count movements routinely, but could raise concerns or be asked about movements at	of late fetal death by a third. (4 to 2.7 per 1000), at 5% level of significance. Statistical analysis Intention to treat analysis. Mean or proportion and the difference between them was calculated for every pair of clusters. The three figures were averaged over all the pairs. Significance was tested with paired t-tests.	Event rate: Difference in means: 2/100 (95% CI): -1.8 to 5.8 <u>Antepartum late fetal death</u> - rate per 1000: Intervention: n clusters = 33 event rate = 2.9/1000 (SE 0.33) n deaths = 99 Control: n clusters = 33 event rate = 2.67/1000 (SE 0.27) n deaths = 100 Difference in means (95% CI): 0.24 (-0.5 to 0.98)	Deviations from intended interventions: Low risk of bias. (Intervention not suitable for blinding). Missing outcome data: Low risk of bias. (Information was available for 91% of women). Measurement of the outcome: High risk of bias. (Anxiety outcome is subjective and self-reported by mothers). Selection of the reported outcome: Unclear risk of bias. Overall risk of bias: Some concern

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
		antenatal visits and obstetricians could give charts to select groups of women if circumstances dictated. Clinicians were asked to respond to reduced movement reports as they thought best appropriate.			
Full citation Norman, JE., Heazell, AEP., Rodriguez, A., Weir, CJ., Stock, SJE., Calderwood, CJ., Cunningham Burley, S., Frøen, JF., Geary, M., Breathnach, F., Hunter, A., McAuliffe, FM., Higgins, MF., Murdoch, E., Ross-Davie, M., Scott, J., Whyte, S., AFFIRM investigators. Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial, Lancet, 392,1629-1638, 2018 **Ref Id** 889473	**Sample size** Clusters: 37 maternity centres enrolled 33 Maternal centres randomised Pregnancies N=409175 Intervention: n=227860 Control: n=157692 **Characteristics** Maternal age: mean (SD) Intervention: 30.2 (5.7) Control: 30.0 (5.8) BMI: n (%) Intervention: Underweight (<18·5 kg/m²): 5107 (2.7%) Normal (≥18·5 to 24·9 kg/m²): 90266	**Interventions** Fetal movement awareness package: A web-based education package was provided to all clinical staff in the participating hospitals, explaining the importance of changes in frequency of fetal movements, 1 month before implementation. Pregnant women were given a fatal movement leaflet at around 20 weeks' gestation. A management plan following reduced fetal movements from 24 weeks' gestation was	**Details** Power analysis Statistical analysis Primary analysis done by intention to treat. Births analysed according to the group they were in – intervention or control – and not whether they had the intervention implemented. Secondary analysis assigned a birth to the control period if the centre did not adhere to the intervention at the time of birth. Stillbirth outcomes summarised a number of stillbirths per 1000 livebirths.	**Results** Odds ratio adjusted for maternal age, multifetal pregnancies, study time period and cluster. Critical outcomes: <u>Admission to neonatal unit</u>: Intervention: 19237 (10-1%) Control: 13029 (10-1%) Adjusted OR (95% CI): 1.02 (0.97–1.07) p=0.504 Absolute effect (95% CI) per 10000 babies: 14 more (28 fewer to 59 more). <u>Perinatal mortality</u>: n/N (per 1000 births) *Still birth at 24 weeks gestation and above, or death within 7 days of life.*	**Limitations** Cochrane risk of bias tool V2: Randomisation process: Low risk of bias. (Computer generation allocation scheme). Deviations from intended interventions: Low risk of bias. (Participants were not blinded, but unlikely to have an effect due to the nature of the intervention). Missing outcome data: Low risk of bias. (0.02% of the data was missing for analysis). Measurement of the outcome: Low risk of bias. (Although assessors were not blinded, the

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
Country/ies where the study was carried out UK (England, Northern Ireland, Scotland and Wales) and Ireland. **Study type** Stepped-wedge cluster randomised controlled trial **Aim of the study** Test that the introduction of a reduced fetal movement (RFM) care package for pregnant women and clinicians increased women's awareness of the need for reporting RFM, and in turn would alter incidence of still birth **Study dates** January 1 2014 – December 31 2016 **Source of funding** Chief Scientist Office, Scottish Government. Tommy's Centre for Maternal and Fetal Health, Sands	(47.3%) Overweight (≥25 to 29·9 kg/m²): 53829 (28.2%) Obese (≥30 kg/m²): 41584 (21.8%) Control: Underweight: 3605 (2.8%) Normal: 63055 (49.0%) Overweight: 35876 (27.9%) Obese: 26074 (20.3%) **Inclusion criteria** Data for all women was collected. **Exclusion criteria** No women were excluded unless they chose not to take part in the study.	put in place, which included a cardiotocography, measurement of liquor volume and a growth scan. Use of an umbilical artery Doppler in addition to the growth scan was encouraged if available. Control: Usual care process in each study site. No further detail provided for specific sites.		Intervention: 1238/227860 (6.21) Control: 923/157692 (6.82) Adjusted OR (95% CI): 0.98 (0.83-1.17) p=0.861 Absolute effect (95% CI) per 10000 pregnancies: 1 fewer (12 fewer to 12 more) Important outcomes: <u>Estimated gestation</u> categories- n/N (%): <37+0 weeks Intervention: 33792/227860 (14.9%) Control: 20966/157692 (13.6%) >37 to ≤39 weeks Intervention: 90767/227860 (40.0%) Control: 59354/157692 (38.5%) >39 weeks Intervention: 102411/227860 (45.2%) Control: 73936/157692 (47.9%) <u>Induction of labour</u> n/N (%) Intervention: 83499/227860 (40.7) Control: 49952/157692 (35.8) Adjusted odds ratio (95%	outcomes did not involve judgement). Selection of the reported result: Low risk of bias. Overall risk of bias: Low risk

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
				CI): 1.05 (1.02, 1.08) p<0.0015 Mode of birth n/N (%): Spontaneous vaginal birth: Intervention: 130658/227860 (57.4) Control: 94337/157692 (59.8) Emergency caesarean section: Intervention: 33996/227860 (14.9) Control: 21865/157692 (13.9) Elective caesarean section: Intervention: 30576/227860 (13.4) Control: 18366/157692 (11.6) Design effect adjustment carried out by authors for outcomes: admission to neonatal unit; perinatal mortality; induction of labour. Design effect adjustment carried out by NGA team for outcomes: estimated gestation; spontaneous vaginal birth, elective caesarean, emergency caesarean.	

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
				Where sample sizes required adjusting for cluster design by the NGA team, an assumed intracluster correlation coefficient (ICC) and the average cluster size were used. ICC=0.05 Average cluster size: 12399 Adjusted sample size = sample size / design effect. Design effect = 1 + (average cluster size – 1) x ICC	
Full citation Saastad, E., Winje, B. A., Stray Pedersen, B., Froen, J. F., Fetal movement counting improved identification of fetal growth restriction and perinatal outcomes--a multi-centre, randomized, controlled trial, 6, e28482, 2011 **Ref Id** 1111817	**Sample size** N=1123 (N=1076 analysed) Control: n=559 (n=532 analysed) Intervention: n=564 (n=544 analysed) Characteristics Maternal age ≥35 years – number (%) Control: 106 (19.9) Intervention: 98 (18.0) Primiparous – number (%)	**Interventions** Fetal movement counting: Women received an information brochure explaining how to use a fetal movement chart. Count to ten method used. Midwife or an obstetrician called women within 2 weeks after starting counting Control:	**Details** Power analysis Estimated sample size of 538 in each arm with 80% power and significance level of 0.05. Statistical analysis Effect size was analysed using Chi-square and Fisher exact tests. Relative risk was included with its 95% confidence intervals.	**Results** Critical outcomes: <u>Transferred to neonatal care unit</u> n/N: Control: 30/532 Intervention: 33/544 RR 95% CI: 1.1 (0.7–1.7) p= 0.765 <u>Perinatal death</u> n/N: Control: 0/532 Intervention: 0/544 p= - RR: -	**Limitations** Cochrane risk of bias tool V2: Randomisation process: Low risk of bias. (Simple randomisation from a computer generated random allocation list. Allocation was concealed). Deviations from intended interventions: Low risk of bias. (The nature of the intervention was not suitable for blinding).

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
Country/ies where the study was carried out Norway **Study type** Randomised controlled trial **Aim of the study** To assess the effects of fetal movement counting on antenatal identification of fetal and pregnancy outcomes. **Study dates** September 2007 - November 2009 **Source of funding** Grants from the Norwegian sudden infant death syndrome and Stillbirth Society, Oslo, Norway	Control: 248 (46.6) Intervention: 228 (41.9) **Inclusion criteria** Norwegian-speaking Singleton pregnancies **Exclusion criteria** Pregnancies where severe anomalies or other causes for considering termination	Standard Norwegian antenatal care.	Comparisons of characteristics (maternal age, parity, marital status and smoking habits) between the study sample and the total population of women delivering in Norway were performed using chi square test. Intention to treat Analyses were performed with intention to treat.	Important outcomes: <u>Gestational age at birth</u> in days- mean (SD): Control: 279 (11.2) Intervention: 280 (10.9) p= 0.321 <u>Induction of labour -</u> Inductions or interventions on fetal indication n/N: Control: 90/532 Intervention: 95/544 RR 95% CI: 1.0 (0.8-1.3) p= 0.812 <u>Mode of birth:</u> Spontaneous vaginal birth n/N: Control: 418/532 Intervention: 431/544 RR 95% CI: 1.0 (1.0–1.1) p=0.792 <u>Elected caesarean</u> n/N: Control: 34/532 Intervention: 29/544 RR 95% CI: 0.8 (0.5–1.4) p= 0.459 <u>Emergency caesarean</u> n/N: Control: 4/532 Intervention: 7/544 RR 95% CI: 1.7 (0.5–5.8) p= 0.383	Measurement of the outcome: Low risk of bias. (Although assessors had knowledge of the allocated interventions, outcomes did not involve judgement). Missing outcome data: Low risk of bias. (Low amount of missing data (4%). Reasons were described, unlikely to have produced bias). Selection of the reported result: Low risk of bias. (only one possible way to record the outcome domains). Overall risk of bias: Low risk
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations**

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
Saastad, E., Winje, B. A., Israel, P., Froen, J. F., Fetal movement counting--maternal concern and experiences: a multicenter, randomized, controlled trial, Birth, 39, 10-20, 2012 **Ref Id** 1111821 **Country/ies where the study was carried out** Norway **Study type** Randomised controlled trial **Aim of the study** To assess the effects of fetal movement counting on maternal concern. **Study dates** September 2007 to November 2009 **Source of funding** Grants from Norwegian sudden infant death syndrome and Stillbirth Society, Oslo, Norway.	N=1123 (N=1013 analysed) Control: n= 559 (n=510 analysed) Intervention: n=564 (n=503 analysed) **Characteristics** Maternal age - mean (+/- SD) Control: 30.2 (+/- 5.1) Intervention: 30.5 (+/- 4.8) p=0.407 Parity Control: 0.8 (+/- 0.9) Intervention: 0.9 (+/- 0.9) p= 0.110 Pre-pregnancy obstetric risk factors - number (%) (Previous fetal growth restriction, stillbirth >21 weeks of gestation, preterm birth, serious preeclampsia, or malformations) Control: 14 (3) Intervention: 17 (3) p=0.145 Pre pregnancy risk factors -general health- number (%)	Intervention: Women received an information brochure which included instructions on how to use a fetal movement chart. Women were asked to count fetal movements daily from gestational week 28. A modified count to ten method was used. Women were contact by a midwife or obstetrician by telephone within the first 2 weeks to ensure the instructions had been interpreted correctly Control: Standard Norwegian antenatal care.	Power analysis Statistical analysis For the Cambridge Worry Scale, effect size was analysed using the Student t test. The mean and SD, difference in mean and 95 percent confidence intervals were included for intervention and control groups. For categorical variables, effect size was analysed using a chi-squared test. Relative risk with 95 percent confidence interval was included. Psychometric characteristics were analysed using the Student t test. Anxiety and depression were dichotomised according to clinical cutoffs and analysed using chi-squared tests. Differences in proportions of categorical variables within the intervention group were analysed	Critical outcomes: <u>Maternal anxiety:</u> Cambridge Worry Scale - mean (SD): (16 item measure, 6 point Likert type scale from 0 to 5. A higher score represents an increased worry. No MID published.) Control: 0.90 (0.62) Intervention: 0.77 (0.55) Difference of 0.14 (95% CI: 0.06–0.21, p < 0.001).	Cochrane risk of bias tool V2: Randomisation process: Low risk of bias. (Randomisation was determined using a computer generated random allocation list. Allocation sequence was concealed). Deviations from intended interventions: Low risk of bias. (The intervention was not suitable for blinding). Measurement of the outcome: High risk of bias. (Subjective outcome completed by mothers). Missing outcome data: Low risk of bias. (>90% of the data was available (continuous outcome)). Selection of the reported result: Low risk of bias. (It is clear the measurements made were reported). Overall risk of bias: Some concern

Evidence tables Study details	Participants	Interventions	Methods	Outcomes	Comments
	Hypertension, chronic renal or coronary disease, known diabetes type I or II, inflammatory and rheumatoid diseases, coagulopathy, epilepsy, or hypothyroidism. Control: 38 (8) Intervention: 37 (7) p= 0.558 **Inclusion criteria** Norwegian speaking women Singleton pregnancies **Exclusion criteria** Pregnancies with fetal malformations which were under consideration of termination at the time of recruitment		using a chi-squared test and included odds ratio with its 95 percent confidence interval. Comparisons of characteristics were analysed using chi-squared tests, between the study sample and total population of women who delivered in Norway. Characteristics compared were maternal age, parity, marital status, and smoking habits. Significance level was set at $p < 0.05$. All analyses were performed according to intention-to-treat.		

CI: confidence interval; ICC: intracluster correlation coefficient; MID: minimally important difference; NGA: National Guideline Alliance; OR: odds ratio; RFM: reduced fetal movements; RR: risk ratio; SD: standard deviation; SE: standard error.

Appendix E – Forest plots

Forest plots for review question: Is fetal movement monitoring from 28 weeks effective?

This section includes forest plots only for outcomes that are meta-analysed. Outcomes from single studies are not presented here; the quality assessment for such outcomes is provided in the GRADE profiles in appendix F.

Appendix F – GRADE tables

GRADE tables for review question: Is fetal movement monitoring from 28 weeks effective?

Table 5: Clinical evidence profile for comparison asking women to count fetal movements versus usual care

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Asking women to count fetal movements	Usual care	Relative (95% CI)	Absolute	Quality	Importance
Maternal anxiety (follow-up 7 weeks; measured with: Cambridge Worry Scale, at week 35; range of scores: 0-5; Better indicated by lower values)												
1 (Saastad 2011)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	503	510	-	MD 0.13 lower (0.2 to 0.06 lower)	⊕⊕⊕O MODERATE	CRITICAL
Maternal anxiety (difference in the mean rate per 100 women reporting anxiety; follow-up 12 weeks; measured with: Self-reported ; Better indicated by lower values)												
1 (Grant 1989)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	31993	36661	-	MD 2 higher (1.8 lower to 5.8 higher)	⊕⊕OO LOW	CRITICAL
Admission to neonatal unit (follow-up 12 weeks)												
1 (Saastad 2011)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[3]	none	33/544 (6.1%)	30/532 (5.6%)	RR 1.08 (0.67 to 1.74)	5 more per 1000 (from 19 fewer to 42 more)	⊕⊕OO LOW	CRITICAL
Perinatal death (follow-up 12 weeks)												
1 (Saastad 2011)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision[4]	none	0/544 (0%)	0/532 (0%)	RD 0.00 (95% CI -0.00 to 0.00).	0 more per 1000 (from 0 fewer to 0 more)	⊕⊕⊕⊕ HIGH	CRITICAL
Antepartum late fetal death (rate per 1000 singleton births; follow-up 12 weeks; Better indicated by lower values)												
1 (Grant 1989)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[2]	none	31648	36231	-	MD 0.24 higher (0.5 lower to 0.98 higher)	⊕⊕⊕O MODERATE	CRITICAL
Gestational age at birth (follow-up 12 weeks; measured with: Days; Better indicated by higher values)												

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Asking women to count fetal movements	Usual care	Relative (95% CI)	Absolute	Quality	Importance
1 (Saastad 2011)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	544	532	-	MD 1 higher (0.32 lower to 2.32 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT
Inductions or interventions on fetal indication (follow-up 12 weeks)												
1 (Saastad 2011)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[3]	none	95/544 (17.5%)	90/532 (16.9%)	RR 1.03 (0.79 to 1.34)	5 more per 1000 (from 36 fewer to 58 more)	⊕⊕OO LOW	IMPORTANT
Spontaneous vaginal birth (follow-up 12 weeks)												
1 (Saastad 2011)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	431/544 (79.2%)	418/532 (78.6%)	RR 1.01 (0.95 to 1.07)	8 more per 1000 (from 39 fewer to 55 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
Elective caesarean (follow-up 12 weeks)												
1 (Saastad 2011)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[3,5]	none	29/544 (5.3%)	34/532 (6.4%)	RR 0.83 (0.52 to 1.35)	11 fewer per 1000 (from 31 fewer to 22 more)	⊕⊕OO LOW	IMPORTANT
Emergency caesarean (follow-up 12 weeks)												
1 (Saastad 2011)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[3]	none	7/544 (1.3%)	4/535 (0.75%)	RR 1.72 (0.51 to 5.85)	5 more per 1000 (from 4 fewer to 36 more)	⊕⊕OO LOW	IMPORTANT

CI: confidence interval; MD: mean difference; NICU: neonatal intensive care unit; RD: risk difference; RR: risk ratio.

[1] *Evidence downgraded by 1 level due to high risk of measurement outcome bias in 1 study.*

[2] *Evidence downgraded by 1 level because 95% CI cross 1 MID for continuous outcomes (0.5 x control group SD, for maternal anxiety =3.9, for antepartum late fetal death =0.75).*

[3] *Evidence downgraded by 2 levels because 95% CI cross 2 MIDs for dichotomous outcomes (0.8 or 1.25).*

[4] *0 events in both arms, therefore precision assessment based on sample size, as n >500, no imprecision.*

[5] *Evidence downgraded by 1 level because 95% CI cross 1 MID for dichotomous outcomes (0.8 or 1.25).*

Table 6: Clinical evidence profile for comparison AFFIRM package versus usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	AFFIRM package	Usual care	Relative (95% CI)	Absolute		
Admission to neonatal unit (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	19237/227860 (8.4%)	13029/157692 (8.3%)	OR 1.02 (0.97 to 1.07)	2 more per 1000 (from 2 fewer to 5 more)[1]	⊕⊕⊕⊕ HIGH	CRITICAL
Perinatal mortality (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	1238/227860 (0.54%)	923/157692 (0.59%)	OR 0.98 (0.83 to 1.16)	0 fewer per 1000 (from 1 fewer to 1 more)[1]	⊕⊕⊕⊕ HIGH	CRITICAL
Estimated gestation <37+0 weeks (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2]	none	33792/227860 (14.8%)	20966/157692 (13.3%)	RR 1.1 (0.74 to 1.64)[3]	13 more per 1000 (from 35 fewer to 85 more)	⊕⊕OO LOW	IMPORTANT
Estimated gestation >37 to ≤39 weeks (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[4]	none	90767/227860 (39.8%)	59354/157692 (37.6%)	RR 1.05 (0.86 to 1.29)[3]	19 more per 1000 (from 53 fewer to 109 more)	⊕⊕⊕O MODERATE	IMPORTANT
Estimated gestation >39 weeks (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	102411/227860 (44.9%)	73936/157692 (46.9%)	RR 0.96 (0.81 to 1.14)[3]	19 fewer per 1000 (from 89 fewer to 66 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
Induction of labour (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious	no serious inconsistency	no serious indirectness	no serious imprecision	none	83499/227860 (36.6%)	49952/157692 (31.7%)	OR 1.05	11 more per 1000 (from 4	⊕⊕⊕⊕ HIGH	IMPORTANT

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	AFFIRM package	Usual care	Relative (95% CI)	Absolute	Quality	Importance
		risk of bias							(1.02 to 1.08)	more to 17 more)[1]		
Spontaneous vaginal birth (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	130658/227860 (57.3%)	94337/157692 (59.8%)	OR 0.90 (0.88 to 0.92)	26 fewer per 1000 (from 20 fewer to 31 more)[1]	⊕⊕⊕⊕ HIGH	IMPORTANT
Elective caesarean section (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2]	none	30576/227860 (13.4%)	18366/157692 (11.6%)	RR 1.13 (0.74 to 1.73)[3]	15 more per 1000 (from 30 fewer to 85 more)	⊕⊕OO LOW	IMPORTANT
Emergency caesarean section (follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2]	none	33996/227860 (14.9%)	21865/157692 (13.9%)	RR 1.09 (0.73 to 1.61)[3]	12 more per 1000 (from 37 fewer to 85 more)	⊕⊕OO LOW	IMPORTANT
Caesarean section (overall, follow-up 16 weeks)												
1 (Norman 2018)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	64572/227860 (28.3%)	40231/157692 (25.5%)	OR 1.09 (1.06 to 1.12)	17 more per 1000 (from 11 more to 22 more)[1]	⊕⊕⊕⊕ HIGH	IMPORTANT

CI: confidence interval; NICU: neonatal intensive care unit; OR: odds ratio; RR: risk ratio.
[1] Relative effect from multivariable model, absolute effect based on relative effect applied to observed event rate.
[2] Evidence downgraded by 2 levels because 95% CI cross 2 MIDs for dichotomous outcomes (0.8 or 1.25).
[3] Relative effect calculated with design effect sample size adjustment due to cluster RCT study design.
[4] Evidence downgraded by 1 level because 95% CI cross 1 MIDs for dichotomous outcomes (0.8 or 1.25).

Table 7: Clinical evidence profile for comparison Mindfetalness versus usual care

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mindfetalness	Usual care	Relative (95% CI)	Absolute	Quality	Importance
Admission to neonatal intensive care unit (follow-up 12 weeks)												
1 (Akselsson 2020)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	1242/19639 (6.3%)	1377/20226 (6.8%)	RR 0.93 (0.86 to 1)	5 fewer per 1000 (from 10 fewer to 0 more)	⊕⊕⊕⊕ HIGH	CRITICAL
Death within 27 days after birth (follow-up 12 weeks)												
1 (Akselsson 2020)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	2/19639 (0.01%)	5/20226 (0.02%)	RR 0.41 (0.06 to 1.91)	0 fewer per 1000 (from 0 fewer to 0 more)	⊕⊕OO LOW	CRITICAL
Perinatal mortality (composite outcome of death within 27 days and stillbirths; follow-up 12 weeks)												
1 (Akselsson 2020)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	35/19639 (0.18%)	34/20226 (0.17%)	pOR 1.03 (0.06 to 16.49)[2]	0 more per 1000 (from 2 fewer to 26 more)	⊕⊕OO LOW	CRITICAL
Gestational age at birth <37+0 weeks (follow-up 9 weeks)												
1 (Akselsson 2020)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	700/19639 (3.6%)	716/20226 (3.5%)	RR 1.01 (0.91 to 1.12)	0 more per 1000 (from 3 fewer to 4 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
Gestational age at birth >41+6 weeks (follow-up 14 weeks)												
1 (Akselsson 2020)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	1015/19639 (5.2%)	1154/20226 (5.7%)	RR 0.91 (0.83 to 0.98)	5 fewer per 1000 (from 1 fewer to 10 fewer)	⊕⊕⊕⊕ HIGH	IMPORTANT
Induction of labour (follow-up 12 weeks)												
1 (Akselsson 2020)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	3747/19639 (19.1%)	4010/20226 (19.8%)	RR 0.96 (0.92 to 1)	8 fewer per 1000 (from 16 fewer to 0 more)	⊕⊕⊕⊕ HIGH	IMPORTANT
Caesarean section (follow-up 12 weeks)												
1 (Akselsson 2020)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	3741/19639 (19%)	4048/20226 (20%)	RR 0.95 (0.91 to 0.99)	10 fewer per 1000 (from 2 fewer to 18 fewer)	⊕⊕⊕⊕ HIGH	IMPORTANT

CI: confidence interval; NICU: neonatal intensive care unit; pOR: Peto odds ratio; RR: risk ratio.
[1] Evidence downgraded by 2 levels because 95% CI cross 2 MID for dichotomous outcomes (0.8 or 1.25).
[2] Relative effect calculated with design effect sample size adjustment due to cluster RCT study design.

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: Is fetal movement monitoring from 28 weeks effective?

A single economic search was undertaken for all topics included in the scope of this guideline. No economic studies were identified which were applicable to this review question. See supplementary material 2 for details.

No economic evidence was identified which was applicable to this review question.

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Appendix H – Economic evidence tables

Economic evidence tables for review question: Is fetal movement monitoring from 28 weeks effective?

No economic evidence was identified which was applicable to this review question.

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: Is fetal movement monitoring from 28 weeks effective?

No economic evidence was identified which was applicable to this review question.

Appendix J – Economic analysis

Economic evidence analysis for review question: Is fetal movement monitoring from 28 weeks effective?

1.1 Introduction

Reducing perinatal mortality is a priority for the NHS and is a mandated objective from the UK government. NHS Saving Babies' Lives Care Bundle 2 (SBLCB) is a bundle designed to provide guidance to providers, commissioners and healthcare professionals to take action to reduce stillbirth and early neonatal death, which together compose perinatal mortality. The bundle brings together four elements of care:

1. Reducing smoking in pregnancy
2. Risk assessment and surveillance for fetal growth restriction
3. Raising awareness of reduced fetal movement
4. Effective fetal monitoring during labour

In 2017, NICE conducted a surveillance report to assess topic areas that may require updating from the 2008 NICE guideline on antenatal care for uncomplicated pregnancies (CG62). One such topic area highlighted in the report was new evidence related to SBLCB. The focus of this evidence review, fetal movement monitoring, is related to element 3 of SBLCB.

A structured fetal movement awareness package, as presented in Norman 2018, has recently become standard care in nearly all NHS trusts. The results from this study did not demonstrate effectiveness for some critical outcomes highlighted in the protocol most importantly admission to NICU and perinatal mortality. It has also been suggested that structured fetal movement awareness packages may be associated with an increase in maternal anxiety and expedited birth and also an increase in costs through an uptake in staff time and an increase in obstetric interventions. Thus, there may be significant changes in costs and health outcomes associated with structured fetal movement awareness packages.

Mindful of this wider context of UK Government policy, the committee felt it was important to consider relevant cost effectiveness evidence when making their recommendations. No existing economic evidence was found in the global health economic search conducted for this guideline. For this reason, de novo economic analysis was undertaken to assess the cost effectiveness of structured fetal movement awareness packages in comparison with not explicitly raising awareness of reduced fetal movement.

1.2 Methods

1.2.1 Cost utility analysis (CUA)

This economic evaluation is conducted in the form of a cost-utility analysis (CUA), with outcomes expressed in terms of the cost per quality-adjusted life year (QALY) gained. The cost effectiveness of an intervention is determined by examining the incremental cost (Ci – Cc) divided by the incremental effect (Ei – Ec), where Ci and Cc represent the cost of the intervention and comparator groups respectively, and Ei and Ec represent the outcomes of the intervention and comparator groups respectively.

The primary effectiveness parameters of this analysis are extracted from Norman 2018 which specified 'awareness of fetal movements and care package to reduce fetal mortality' (AFFIRM) as the intervention, compared with a control period in a stepped wedged design randomised controlled trial (RCT). In this economic analysis, AFFIRM, representing the

structured fetal movement awareness package was set as the comparator as this represents current UK practice and 'no formal awareness package' (NFA) was set as the intervention.

The main result is expressed as the incremental cost effectiveness ratio (ICER) and incremental net monetary benefit (iNMB). The analysis was conducted from the perspective of the NHS and Personal Social Services (PSS), as outlined in the NICE Reference Case (NICE 2014).

These results are presented in two forms:

- Deterministic analysis: Results computed from the point estimates of model parameters
- Probabilistic sensitivity analysis (PSA): Uncertainty in model input parameters reflected in results by sampling from appropriate statistical distributions.

1.2.2 Setting and population

The model setting was for the NHS and the population was all unselected low-risk pregnancies, as in accordance with the protocol of the clinical evidence review. It was assumed that the women were aged 31 years, reflecting the mean age of women giving birth in England and Wales in 2016 (ONS 2018).

1.2.3 Intervention considered

The following treatment strategies are considered in this analysis are:

- No formal awareness package (NFA)
- Awareness of formal fetal movement monitoring (AFFIRM)
- Mindfetalness

The treatment strategies above were compared in three different way during the analysis.

- AFFIRM versus NFA
- Mindfetalness versus NFA
- AFFIRM versus Mindfetalness versus NFA

AFFIRM versus NFA was informed from the Norman 2018 study included in the clinical evidence review. In this study, participating maternity hospitals were grouped and randomised to one of nine implementation dates at 3 month intervals. Each participating hospital had 3 observation periods: a control period; a washout period between the intervention period; and the intervention period itself. The primary analysis was conducted according to the intention-to-treat principles. Comparisons of pregnancy outcomes for births during the control and intervention period were used to inform the effectiveness of the intervention (set as AFFIRM in the trial).

The AFFIRM package involves a leaflet for pregnant women at 20 weeks' gestation. The aim of the leaflet is to raise awareness of the importance of monitoring fetal movements and reporting reduced movements. The package also includes a management plan for hospitals to conduct a cardiotocography (CTG) and a growth scan to estimate fetal weight and abdominal circumference.

The management plan for NFA was not stated, however, the committee believed that it would be broadly the same as the AFFIRM trial and aligned with recommendations set in the relevant Royal College of Obstetricians and Gynaecologists (RCOG) guidance on reduced fetal movements (Green-top guideline 57).

The differences between the two interventions are therefore nuanced in that there is a similar management strategy for each, though the management plan for AFFIRM makes a more explicit case for conducting CTGs and ultrasound scans which may entail differing resource

estimates compared with NFA. Also, for babies suspected at risk of stillbirth under the AFFIRM, early birth is recommended which may cause differences in costs and outcomes.

These two interventions reflect the primary analysis as they are directly relevant to the UK NHS decision making context. The clinical evidence review also identified a cluster RCT, set in Sweden that examined whether a method for raising women's awareness of fetal movements, 'Mindfetalness', can impact upon pregnancy outcomes (Akselsson 2020). The comparator was routine care in a Swedish setting. For women registered at a clinic randomised to Mindfetalness, women were instructed to trust their intuition (rather than formally count kicks) and seek care if they feel fetal wellbeing may be compromised. Specifically, women are asked to lie on one's side for 15 minutes per day when the fetus is awake, monitoring the character, strength and frequency of the movements. Again, the management plan for NFA was not specified and was assumed to be identical to that used in the UK.

An important difference between Norman 2018 and Akselsson 2020 is that the former includes an awareness package, AFFIRM, that is aimed at both clinicians and pregnant women. By contrast, Mindfetalness is aimed solely at pregnant women.

Baseline values for the pairwise analyses were taken from the relevant study. For the three-way comparison the baseline values in Norman 2018 were used for both interventions and the risk ratios Akselsson 2020. Norman 2018 baseline accurately reflects the current UK practice, where as there may be systematic differences in the provision of healthcare, especially how to respond to concerns about fetal movement in Swedish maternity hospitals particularly around whether to induce labour and the mode of birth. In the baseline outcomes are better (lower NICU admission, stillbirth etc) in the Akselsson 2020 cmpared to Norman 2018 suggesting differences in population characteristics and/or the type of care received. There are also important differences in the way resource use is reported that would bias comparisons in a three-way comparison. For this reason, separate pairwise comparisons were made comparing the structured formal awareness package (AFFIRM, Mindfetalness) with NFA alongside the three-way analysis for which results should be interpreted with caution.

1.2.4 Model structure

The model was structured as an incremental analysis of the two identified strategies against routine care: AFFIRM versus NFA and Mindfetalness versus NFA. The same structure was used for the three-way analysis

Perinatal mortality was identified as a critical outcome in the protocol of this evidence review. Therefore, a lifetime time horizon was considered for the babies in the model to include all future life years gained between the interventions. Costs and QALYs for women were only calculated for 1 year which was considered adequate to capture all differences in costs and benefits, as a result of the interventions, for this group.

It is important to note that stillbirth, rather than perinatal mortality which includes early neonatal death, has been the explicit focus of SBLCB and other key stakeholders in this topic area. For this reason, the model included analyses where both perinatal mortality and stillbirth were used to inform future life years.

1.2.5 Clinical parameters and baseline risk

Model parameters were taken directly from the two relevant studies given both covered the time horizon of the interventions fully. Other outcomes such as those relevant to maternal or baby morbidity were not included as there was no evidence identified for these outcomes in the clinical evidence review.

The outcomes included in the base-case model are listed below:

- admission to neonatal intensive care unit (NICU)
- perinatal mortality (stillbirth in a separate analysis)
- induction of labour
- spontaneous vaginal birth
- assisted vaginal birth
- elective caesarean section
- emergency caesarean section

No strong evidence was identified which associated induction of labour with an increase in any particular mode of birth. The percentage of women having an induction of labour therefore did not alter the probabilities of mode of birth and both probabilities were considered mutually exclusive. Likewise there was no direct link between mode of birth and probability of perinatal mortality or admission to NICU.

These outcomes and their corresponding baseline risk are presented in Table . The baseline risk represents the risk for NFA, as informed by rearranging the relative risk estimates in the Norman trial. Included in the table are the relevant sampling distribution parameters used for probabilistic sampling in the probabilistic sensitivity analysis.

Table 8: Clinical outcomes and baseline probabilities for no formal awareness package

Outcome	Value	α	β	Probabilistic Distribution [b]	Source
NFA versus AFFIRM					
Admission to NICU	0.083	13029	144663	Beta	Norman 2018
Perinatal mortality [a]	0.006	923	156769	Beta	Norman 2018
Stillbirth [a]	0.004	691	157001	Beta	Norman 2018
Induction of labour	0.317	49952	107740	Beta	Norman 2018
Spontaneous vaginal birth	0.598			Dirichlet	Norman 2018
Assisted vaginal birth	0.146			Dirichlet	Norman 2018
Elective caesarean section	0.117			Dirichlet	Norman 2018
Emergency caesarean section	0.139			Dirichlet	Norman 2018
NFA versus Mindfetalness					
Admission to NICU	0.066	1344	18882	Beta	Akselsson 2020
Perinatal mortality [a]	0.002	34	20192	Beta	Akselsson 2020
Stillbirth [a]	0.001	29	20197	Beta	Akselsson 2020
Induction of labour	0.193	3909	16317	Beta	Akselsson 2020

Outcome	Value	α	β	Probabilistic Distribution [b]	Source
Spontaneous vaginal birth	0.679			Dirichlet	Akselsson 2020
Assisted vaginal birth	0.126			Dirichlet	Akselsson 2020
Elective caesarean section	0.104			Dirichlet	Akselsson 2020
Emergency caesarean section	0.091			Dirichlet	Akselsson 2020

(a) Each outcome is substituted in a separate analysis
(b) Beta distribution constrains sampled probabilities between 0 and 100%

1.2.6 Effectiveness estimates

The reported AFFIRM outcomes, along with their 95% confidence intervals (CIs) are displayed in Table . These are expressed as risk ratios (RRs) and are reported from the trial perspective where AFFIRM is the intervention. These relative treatment effects were applied to the baseline risk to provide an estimate of the risk of each outcome of interest for AFFIRM. Utilising the CIs of the RRs, a log-normal distribution was assigned to each RR when sampling in the probabilistic analysis.

Table 9: AFFIRM effectiveness estimates

Outcome	RR	Lower value/limit of 95% CI	Upper value/limit of 95% CI	Distribution	Source
Admission to NICU	1.02	0.97	1.07	Log-normal	Norman 2018
Perinatal mortality [a]	0.98	0.83	1.17	Log-normal	Norman 2018
Stillbirth [a]	0.90	0.75	1.07	Log-normal	Norman 2018
Induction of labour	1.05	1.02	1.08	Log-normal	Norman 2018
Spontaneous vaginal birth	0.90	0.88	0.92	Log-normal	Norman 2018
Elective caesarean section	1.13	0.74	1.73	Log-normal	Norman 2018
Emergency caesarean section	1.09	0.73	1.61	Log-normal	Norman 2018

(a) Each outcome is substituted in a separate analysis

Effectiveness estimates for the Mindfetalness intervention were extracted from Akselsson 2020 and are displayed in Table . These were multiplied against the baseline risk estimates informed from the AFFIRM trial, assuming these baseline estimates best reflected standard UK practice. However, Akselsson also included data on the number of unscheduled visits to clinics owing to decreased fetal movements.

Table 10: Mindfetalness effectiveness estimates

Outcome	RR	Lower value/limit of 95% CI	Upper value/limit of 95% CI	Distribution	Source
Admission to NICU	0.93	0.86	1.00	Log-normal	Akselsson 2020
Perinatal mortality [a]	1.06	0.84	1.34	Log-normal	Akselsson 2020
Induction of labour	0.96	0.92	1.00	Log-normal	Akselsson 2020
Spontaneous vaginal birth	1.02	1.01	1.03	Log-normal	Akselsson 2020
Elective caesarean section	0.94	0.88	0.99	Log-normal	Akselsson 2020
Emergency caesarean section	0.97	0.91	1.03	Log-normal	Akselsson 2020
≥ 1 Unscheduled visits [b c]	1.72	1.57	1.87	Log-normal	Akselsson 2020

(a) This value combines stillbirth (Apgar score of 0)[Total events: Mindfetalness=33, routine care=29] and neonatal mortality [Mindfetalness=2, Routine care=5] to estimate a risk ratio for perinatal mortality. The value in the clinical evidence review, reported as an odds ratio and adjusting for cluster effects was extremely wide giving very wide uncertainty in the economic model results. For this reason an unadjusted risk ratio was used for the analysis which assumes no differences in clusters in the trial.

(b) Number of unscheduled visits due to decreased fetal movements. The RR is for 1 or more visits. Costs were weighted according to the number of >1 visits to maternity units.

(c) The AFFIRM trial did not include data on number of unscheduled visits. Therefore, to maintain consistency in a pairwise comparison, the RR was multiplied against its corresponding baseline risk, informed from the Mindfetalness trial: 772/ (772 + 19454) This equals a baseline risk of 3.82%.

1.2.7 Costs and resource use

1.2.7.1 Outcome costs

The costs considered in the model reflect the perspective of the analysis, thus only costs that are relevant to the UK NHS and personal social services perspective (PSS) were included. This costing perspective is in accordance with the NICE Reference Case (NICE 2014). The costing year was 2019. The main cost inputs were attached to the outcomes in the trials and were mostly informed from the most up to date National Schedule of NHS Costs (NHS Improvement 2019) [previously NHS Reference Costs]. In addition, it was assumed each intervention included costs associated with providing the intervention itself, based on differing estimates of healthcare professionals time and resource use. Costs were not discounted as all relevant costs occurred within the relatively short time horizon of the intervention. Table11 displays all the costs included in the model.

The cost of stillbirth was obtained from a UK cost-of-illness study (Campbell 2018). A direct cost for neonatal mortality is not specified in the National Schedule of NHS Costs. However, the committee advised that all neonatal deaths would have incurred an admission to high dependency units. Therefore, these costs were separated from the neonatal care costs attributed to the outcome 'NICU admissions' to provide an estimation for the costs of neonatal mortality. The unit cost for perinatal mortality was computed as a weighted average of the proportion of 'neonatal deaths and 'stillbirths' in the UK (Draper 2019). The weighted average length of stay in NICU was also informed from the National Schedule of NHS Costs and was multiplied with the relevant unit cost.

Table11: Costs associated with model outcomes

Cost variable	Unit cost	Standard error	alpha	beta	Probability distribution [a]	Source
Admission to NICU [b]	£615	£61	-	-	Normal	National schedule of NHS costs 2018-2019
Neonatal mortality	£1247	£124	-	-	Normal	National schedule of NHS costs 2018-2019
Stillbirth	£4569	-	25	183	Gamma	Campbell 2018
Induction of labour	£267	-	25	11	Gamma	Alfirevic 2016
Spontaneous vaginal birth	£2009	£201	-	-	Normal	National schedule of NHS costs 2018-2019
Assisted vaginal birth	£2745	£275			Normal	National schedule of NHS costs 2018-2019
Elective caesarean section	£3948	£395	-	-	Normal	National schedule of NHS costs 2018-2019
Emergency caesarean section	£5368	£537	-	-	Normal	National schedule of NHS costs 2018-2019
Perinatal mortality [c]	£4,503	-	-	-	Indirectly sampled	National schedule of NHS costs 2018-2019
Litigation costs associated with stillbirth	£848	-	-	-	Not sampled	Campbell 2018

(a) A normal distribution was assumed for costs extracted from the National Schedule of NHS costs as this is based on a large number of data entries from Health Resource Groups (HRGs). A gamma distribution was assumed for costs extracted from Campbell 2018 and SBL report as it was deemed that this cost data would be right skewed.

(b) The unit cost for admission to NICU is multiplied by the average length of stay in such units in the model.

(c) Perinatal mortality is composed of the cost of stillbirth and a weighted unit cost of neonatal mortality. The unit cost of neonatal mortality is informed as being admission to high dependency NICU units. This unit cost is multiplied by the average length of stay in these more intensive units.

It should be noted that the costs of stillbirth obtained from Campbell 2018 were mostly composed of indirect costs associated with aftercare. Costs outside an NHS and PSS perspective have been excluded from the analysis. The cost components informing the unit cost of stillbirth in this model are broadly categorised as:

- care provided at the time that an antepartum stillbirth is suspected and confirmed
- immediate postpartum care
- parental anxiety and depression
- experiences of healthcare professionals such as receiving treatment owing to traumatic experiences of providing care
- antenatal care for pregnancies occurring within 12 months of a prior stillbirth
- outcome of pregnancies occurring within 12 months of a prior stillbirth
- excess preterm live births.

Campbell also reported values for litigation costs associated with a stillbirth. Whilst these costs are excluded from the base-case analysis, they were considered in a sensitivity analysis.

Obtaining the cost of induction was challenging since this cost is not reported independently from other related birth costs. The 'Evaluation of the Implementation of the Saving Babies Lives Care Bundle in early adopter NHS Trusts in England' report includes some resource impact analysis and unit costs related to the provision of the whole SBLCB (Widdows 2018). Included is a reported increase in induction of labour associated with the whole bundle elements and includes a unit cost of £847 per induction. There are two issues with using this unit cost in this analysis. Firstly, it is not clear how this unit cost has been derived and may include double counting with other modes of birth. Also, the unit cost is attributed to all elements of the SBLCB, rather than just the 4th element of the bundle of interest in this evidence review. For this reason, the unit cost of induction of labour was extracted from Wastlund 2019, which in turn sourced this unit cost from Alfirevic 2016.

1.2.7.2 Management strategy costs

The incremental nature of the analysis meant the model sought to capture the difference in costs attributed to NFA as opposed to AFFIRM. For both formal awareness packages, the management strategy is that a woman would undergo a CTG, followed by an ultrasound scan upon clinical suspicion of reduced fetal movement (RFM). As noted, resource use was not reported in the AFFIRM trial. However, the Saving Babies' Lives (SBL report) indicated that the care bundle saw a relative increase in the number of ultrasound scans in trusts after implementation. This estimate is highly uncertain as it is calculated from including all elements of the care bundle, and therefore will be an overestimate. The committee acknowledged this uncertainty, though were unanimous that AFFIRM would entail an increase in ultrasound scans from their own professional experience. Owing to the inherent uncertainty in the plausibility of this assumption, specific sensitivity analysis was conducted at differing relative increments to assess the impact on the overall cost effectiveness results.

A unit cost of a CTG and differing estimates of associated resource use was not found in a search of typical costing sources, nor the grey literature. However, the committee advised that a conservative estimate would be to assume that every woman whom had undergone an ultrasound would have had a CTG prior. Extra time would be required from a midwife to both operate a CTG and discuss the results. This extra resource use is therefore reflected in the base case analysis. The cost of a Band 6 midwife was extracted from the Personal Social Services Research Unit's (PSSRU) report (Curtis and Burns 2019). Table12 displays the costs related to the treatment strategies and Table13 the associated resource use estimates.

Table12: Units costs related to management strategy

Cost variable	Unit cost	Standard error	alpha	beta	Probability distribution	Source
Information leaflet	£0.10	-	-	-	Not sampled	SBL Report
Ultrasound scan	£58	£124	-	-	Normal	National Schedule of NHS Costs 2018-2019
Band 6 midwife (hourly) [b]	£46	-	25	183	Gamma	PSSRU 2019
Antenatal routine	£426	£85			Gamma	National Schedule of NHS

Cost variable	Unit cost	Standard error	alpha	beta	Probability distribution	Source
observation [a]						Costs 2018-2019

(a) Applied to the effect estimate ≥ 1 Unscheduled visits. This cost estimate is only attributed to the Mindfetalness intervention in comparison with NFA as a separate analysis.
(b) The committee advised that a Band 6 midwife cost estimate would be most appropriate for this analysis

Table13: Awareness of formal fetal movement monitoring and no formal awareness resource use

Parameter	Value	Source
Scans in NFA (per person)	3.51	SBL Report
Scans in AFFIRM (per person)	4.35	SBL Report
Extra midwifery time in AFFIRM	50 minutes	Committee assumption [a]

(a) The committee advised that this would be a conservative assumption and assuming that no further contact with an Obstetrician is required.

There was no data found to attribute resource differences for Mindfetalness in the form of a CTG or ultrasound scan. However, the study did report estimates on the number of unscheduled visits to a maternity centre owing to decreased fetal movements. It is important to note that the Mindfetalness treatment strategy is aimed solely at pregnant women rather than medical professionals as well. Also, the management costs associated from differing estimates in unscheduled visits differs to estimates for CTG and ultrasound scans attributed to AFFIRM and NFA. For this reason, the study is not compared in a like-for-like comparison, but as a separate analysis. In this instance, the base case was assumed to be NFA.

1.2.8 Quality-adjusted life years

As recommended in the NICE reference case, the model estimates effectiveness in terms of QALYs. These are estimated by combining the life year estimates with utility values (or quality of life weights) associated with being in a particular health state, in this instance with the clinical outcomes. Utility values are on a scale of 0 (death) to 1 (perfect health).

The utility values used to inform QALYs in this analysis are presented in Table14. It was assumed that an averted neonatal death and stillbirth would result in a normal life expectancy of 81 years, estimated as a weighted average of male and female life expectancy (ONS 2019). It was additionally assumed that each year of life lived would be at a health state utility of 0.860 for males and 0.850 for females (Kind 1999). In accordance with the NICE guideline manual, a discount rate of 3.5% was applied to all future years of life.

Mode of delivery outcome utilities were informed from Petrou 2017 which derived preference-based, EQ-5D utilities from 2,161 mothers in England. The standard errors from this study were utilised to inform sampling from a Beta distribution, constraining sampled values of utilities on a scale between 0 and 1 in the probabilistic analysis.

Utilities were not considered for other relevant outcomes such as maternal or baby morbidity as the clinical review did not elicit any data of these outcomes and the committee did not identify them as critical or important outcomes in the protocol of the accompanying clinical evidence review. Caesarean delivery was stratified by ‘maternal or fetal compromise’ and ‘no maternal or fetal compromise’ in Petrou 2017. This were assigned to elective and emergency caesarean births respectively in our analysis. Caesarean delivery results in lower quality of life compared to other forms potentially as a result of operative complications. It seems counterintuitive that elective caesarean births result in lower quality of life compared to emergency. Petrou 2017 hypothesises this may be as a result of less sustained support

received in the elective group although the design of the study does not allow for biological and psychosocial elements to be explored fully.

Table14: Utilities attributed to model outcomes

Utility	Mean	Standard error	Probability distribution	Source
Average UK male utility value (all ages) [a]	0.860	0.006	Beta	Kind 1999
Average UK female utility value (all ages) [a]	0.850	0.005	Beta	Kind 1999
Spontaneous vaginal birth	0.929	0.006	Beta	Petrou 2017
Assisted vaginal birth	0.943	0.007	Beta	Petrou 2017
Elective caesarean	0.905	0.014	Beta	Petrou 2017
Emergency caesarean	0.924	0.012	Beta	Petrou 2017

(a) Utility value used to inform discounted lifetime QALYs for perinatal mortality

Maternal anxiety was outlined as a critical outcome in the protocol of this evidence review. Relevant utility data was not found for this population and outcome, however, the committee were all in agreement that, in their professional experience, a high proportion of women would likely experience some degree of maternal anxiety in any formal fetal movement treatment strategy. The RCOG Green Top guideline 57 also identifies maternal anxiety as associated with formal fetal movement monitoring. The SBL 2018 report highlighted that around a third of women reported anxiety as result of receiving a leaflet on RFM (the same leaflet as distributed in the AFFIRM study). In this analysis, it was assumed that 30% of women undergoing AFFIRM would experience additional anxiety as compared with NFA.

It was assumed, using the EQ-5D calculator (Szende 2007) that otherwise healthy women would experience a decrement of 1 on the EQ-5D-3L scale in the anxiety/depression domain. This decrement was applied to the proportion of women that would experience anxiety, keeping all else constant. This decrement was attributed as being from:

"I am not anxious or depressed"

To

"I am moderately anxious or depressed"

This approach was presented to the committee and was deemed to be a reasonable assumption to make. The utility decrement was estimated with values from the UK general public and remained constant for 133 days, the duration of the AFFIRM treatment strategy.

A similar approach was used to estimate QALY detriments for a mother as a result of perinatal mortality or stillbirth. For this estimate the anxiety/depression domain was moved to its lowest value "I am extremely anxious or depressed. It was assumed that this decrement would occur for 1 year.

The decrements were subtracted from the average EQ-5D value of females aged between 25-34 to reflect the average age of birth for women in England, 31 years of age (ONS 2019). The values used in this analysis are shown in Table15.

Owing to this assumption not being derived from published data, sensitivity analysis was conducted where the model was run without including this decrement.

Table15: Utilities attributed to maternal anxiety

Utility	Mean	Alpha/low value	Beta/high value	Standard error	Probability distribution	Source
Average UK female utility value (25-34)	0.930	739	56	0.009	Beta	Kind 1999
EQ-5D utility decrement owing to maternal anxiety	0.082[a]	0.066	0.098	-	Uniform [b]	Assumption [c]
EQ-5D utility decrement owing to perinatal death or stillbirth	0.516 [a]	0.413	0.620	-	Uniform [b]	Assumption [c]

(a) Attributed as a utility decrement in the model.
(b) Uniform distribution deemed most appropriate for PSA sampling as no data available on variance. Values constrained between the specified low and high value which is 20% ± the mean value
(c) Calculated from Szende 2007 EQ-5D calculator using the UK tariff.

1.3 Data analysis and presentation of results

1.3.1 Deterministic results

The primary analysis is run with perinatal mortality as a critical outcome instead of stillbirth as this was identified in the protocol of the accompanying clinical evidence review. The results are presented in two formats: i) In the form of a deterministic analysis and; ii) in the form of a probabilistic sensitivity analysis (PSA).

In a deterministic analysis, data are analysed from their reported point estimates; results are presented as total costs and QALYs associated with each treatment strategy assessed.

In addition, a series of one-way sensitivity analysis were also undertaken. In this type of analysis, a single parameter is varied according to a pre-specified high/low value, whilst holding all other inputs constant at their deterministic value. The degree to which varying one input impacts on the mean iNMB are stacked in rank order and have an appearance of a 'Tornado'. The values used in the analysis are displayed in Table16. A two-way sensitivity analysis was also conducted on all possible configurations of ultrasound scans per person between the two interventions. Further sensitivity and scenario analysis, based on differing parameter estimates were also conducted. A rationale for selected parameters is displayed in Table17.

The base-case results focus on NFA versus AFFIRM as these interventions matched the protocol of the evidence review and were the best reflection of UK practice. However, pairwise comparisons between Mindfetalness, AFFIRM and NFA are made in a separate analyses.

Table16: One-way sensitivity inputs

Variable ±	Low Value	High Value
Admission to NICU risk ratio	0.97	1.07
Perinatal mortality risk ratio	0.83	1.17
Induction of labour risk ratio	1.02	1.08

Variable ±	Low Value	High Value
Spontaneous vaginal birth risk ratio	0.88	0.92
Elective caesarean section risk ratio	0.74	1.73
Emergency caesarean section risk ratio	0.73	1.61
Perinatal mortality cost	£4,713	£7,069
NFA cost	£271	£406
AFFIRM cost	£335	£503
Spontaneous vaginal birth utility	0.883	0.976
Assisted vaginal birth utility	0.929	0.956
Elective caesarean section utility	0.860	0.950
Emergency caesarean section utility	0.878	0.970
Maternal anxiety utility decrement	0.066	0.098
Perinatal death/stillbirth utility	0.412	0.619

± The high/low values for risk ratios are informed by each variable's low/high confidence interval. Utilities were varied by 5% of their deterministic value so as to not cross over 1. All cost values were varied at 20% of their deterministic value.

Table17: Scenario analysis rationale

Parameter varied	Default parameter value	New value	Rationale
1. Perinatal mortality changed to stillbirth	0.98	0.90	The protocol for this evidence review highlighted perinatal mortality as a critical outcome. However, SBLCB and relevant stakeholders may have a particular interest in stillbirth. Therefore, the model was run at stillbirth in both a deterministic analysis and PSA.
2. Litigation costs associated with perinatal mortality to be included	£4569	£5891	Litigation costs associated with stillbirth (and therefore also a contributor to perinatal mortality) are outside the NHS and PSS perspective. However, these costs may be of relevant interest to some stakeholders
3. Induction of Labour Costs	£267	£847	The higher figure (£847), obtained from the SBL report, was not used in the base case analysis as it was

Parameter varied	Default parameter value	New value	Rationale
			deemed likely that this figure includes double counting with mode of deliveries.
4. Not including maternal anxiety or perinatal mortality/stillbirth decrement	0.082/0.516 [a]	Not including the decrement	This value represents an assumption of a critical outcome of the protocol, though was the only utility value not informed by published data.

(a) Decrement value as well as the corresponding time spent in the health state are disregarded in this scenario to have no impact on model output

1.3.2 Probabilistic sensitivity analysis

A PSA was undertaken using Monte Carlo simulation in order to reflect uncertainty inherent in pre-specified model parameters by sampling from an assigned probability distribution of each parameter. For each simulation, the resulting costs, QALYs and resulting ICER are computed. This process is repeated numerous times (n=1000), resulting in an average ICER for all simulations and the likelihood of cost effectiveness.

The results of the PSA are presented graphically onto a cost effectiveness plane against a cost effectiveness threshold of £20000 per QALY. The results are also presented in the form of a cost effectiveness acceptability curve (CEAC) which demonstrates the probability of cost effectiveness of each treatment strategy against numerous thresholds.

The base case analysis runs the PSA with perinatal mortality set as one of the critical outcomes in the model - reflecting the protocol of this evidence review. In order to incorporate wider UK policy making concerns which centre specifically around stillbirth, an additional deterministic set of results and PSA was conducted for stillbirth as a substitute for perinatal mortality. A separate set of deterministic results and PSA were also conducted for the Mindfetalness compared with NFA.

1.3.3 Validation of the economic model

The economic model was developed by the health economist in collaboration with members of the guideline committee. Committee members were consulted for the conceptual structure of the model and for their expert opinion for parameters for which published data could not be found. As part of the model validation, all inputs, model formulae and coding were systematically checked. This was done by setting input parameters to null and extreme values, examining whether the results changed in the expected direction. To some degree, this is also displayed visually in the Tornado analysis. In addition, the model output and results were assessed by another health economist and a backlog of previous model versions were recorded.

1.4 Results

The results should be interpreted as follows. If the analysis conducted demonstrates that an intervention is less costly and more effective, it is classified as ‘dominating’ the comparator. A typical scenario is where an intervention is more effective but also costlier, in which case an ICER is considered as a measure of whether the extra cost of an intervention is an efficient use of resources for the NHS.

1.4.1 Base Case Results

Table18 shows the base case deterministic results for NFA compared to AFFIRM. It is pertinent to note that NFA was set as the intervention in this analysis as AFFIRM currently represents most recent UK practice. The model estimated that NFA is less expensive than AFFIRM and is marginally more effective. Thus, NFA can be seen to 'dominate' AFFIRM, meaning that AFFIRM would not be the cost effective option. The results of the PSA are in accordance with the deterministic results, as displayed in *ICER: Incremental Cost Effectiveness Ratio; NFA: No Formal Awareness Package; QALY: Quality-adjusted Life Years.*

Table19

Table18: Deterministic (base-case) results: No formal awareness package (NFA) versus Awareness of fetal movements package to reduce fetal mortality (AFFIRM)

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER**
AFFIRM	£3,593		24.283		-
NFA	£3,411	-£182	24.290	0.006	**Dominant**

ICER: Incremental Cost Effectiveness Ratio; NFA: No Formal Awareness Package; QALY: Quality-adjusted Life Years.

Table19: Probabilistic (base-case) results: No formal awareness package (NFA) versus Awareness of fetal movements package to reduce fetal mortality (AFFIRM) [1000 simulations]

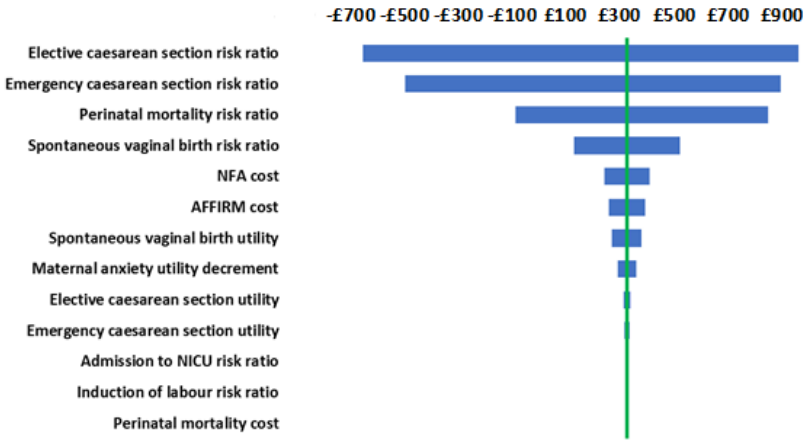
	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER (n=1000)**
AFFIRM	£3,451		24.283		-
NFA	£3,294	-£158	24.290	0.007	**Dominant**

ICER: Incremental Cost Effectiveness Ratio; NFA: No Formal Awareness Package; QALY: Quality-adjusted Life Years.

1.4.1.1 Deterministic sensitivity analysis

The results of a series of one-way sensitivity analyses, where NFA is compared with AFFIRM, are displayed in Figure 2. This analysis displays the impact on cost effectiveness to a low/high change of the variables listed in Table16, holding all other inputs as constant at their default values. The green line in the middle represents the iNMB of the base-case analysis. The wider blue bars indicate the variables that have the greater effect on the model output.

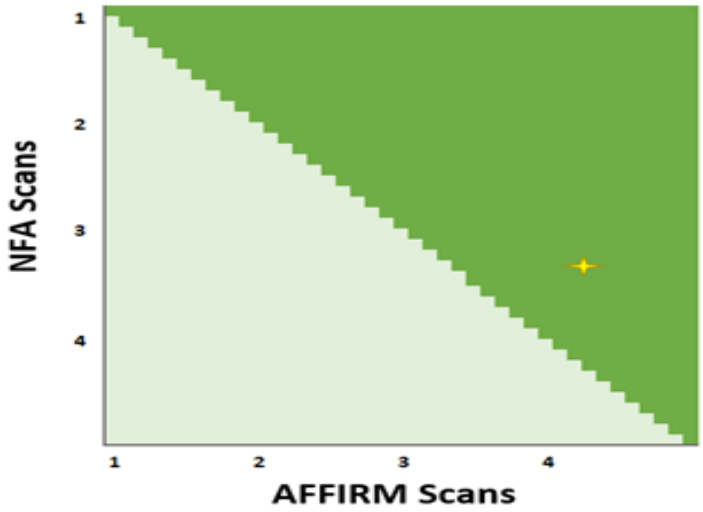
Figure 2: Tornado diagram displaying the effect of a high/low value of each parameter on the incremental net monetary benefit, set at £20,000 per QALY: NFA versus AFFIRM



NFA: No Formal Awareness Package; NICU: Neonatal Intensive Care Unit

Further deterministic sensitivity analysis was conducted on other points of uncertainty in various model parameters. A graphical representation of a series of two-way sensitivity analysis of various estimates of ultrasound scans in both NFA and AFFIRM are presented in Figure 3. Dark green cells show combinations for which NFA is dominant. Lighter green cells show combinations for which NFA is cost effective at £20,000 per QALY gained, though with NFA costing more than AFFRM. Hence, the light green cells represent ICERs less than £20,000. The yellow star highlights the configured values used in the base case analysis. Even at extreme values, in no instance is AFFIRM cost effective.

Figure 3: Two-way sensitivity analysis: ultrasound scans in NFA and AFFIRM



The results of the various scenario analysis are displayed in Table20 . It is important to note that the results of all deterministic sensitivity analyses, whilst a useful check for model robustness, should be interpreted with caution. The assumptions of differing estimates are essentially arbitrary and not all the values tested are equally valid. Therefore, the results of the deterministic analysis should be viewed in conjunction with the results of the PSA.

Table20: Scenario analysis results

Parameter changed	Default ICER [a]	Scenario ICER
1. Perinatal mortality changed to stillbirth	ICER: Dominant	ICER: Dominant
2. Litigation costs associated with perinatal mortality to be included	ICER: Dominant	ICER: Dominant
3. Induction of Labour Costs	ICER: Dominant	ICER: Dominant
4. Not including maternal anxiety decrement	ICER: Dominant	ICER: Dominant

(a) Where the default results are always constant
ICER: Incremental Cost Effectiveness Ratio,

1.4.1.2 Probabilistic sensitivity analysis

The results of the PSA, based on 1000 Monte Carlo simulations of the model are displayed in Table20 and Table21. The mean iNMB is based on a cost effectiveness threshold of £20,000 per QALY gained. A positive iNMB can be interpreted as NFA, set as the intervention in the analysis, as being cost effective.

Table21: Mean incremental net monetary benefit and the probability of cost effectiveness

Pairwise comparison	Mean iNMB (threshold=£20k)	Probability NFA is cost effective (n=1000)
PSA1: NFA versus AFFIRM (perinatal mortality)	£289	81%

iNMB: Incremental Net Monetary Benefit, NFA: No Formal Awareness Package, PSA: Probabilistic Sensitivity Analysis.

Figure 4 displays the cost effectiveness plane of the individual simulations that generated the probabilistic result for NFA versus AFFIRM. The yellow plot represents the average of all simulations and the red line represents the cost effectiveness threshold at £20,000 per QALY. The results of the PSA are also displayed on a CEAC in Figure 5, summarising the impact of uncertainty on the results of the model. The graph includes a range of cost-effectiveness thresholds on the horizontal axis against the probability that the intervention will be cost-effective at a particular threshold on the vertical axis.

Figure 4: Cost effectiveness plane: No formal awareness package (NFA) versus Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): perinatal mortality

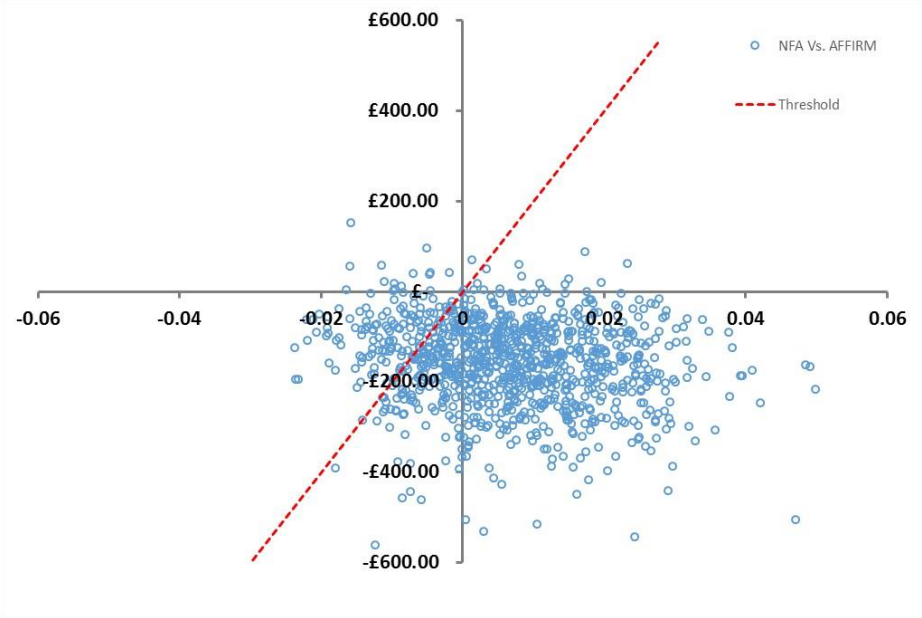
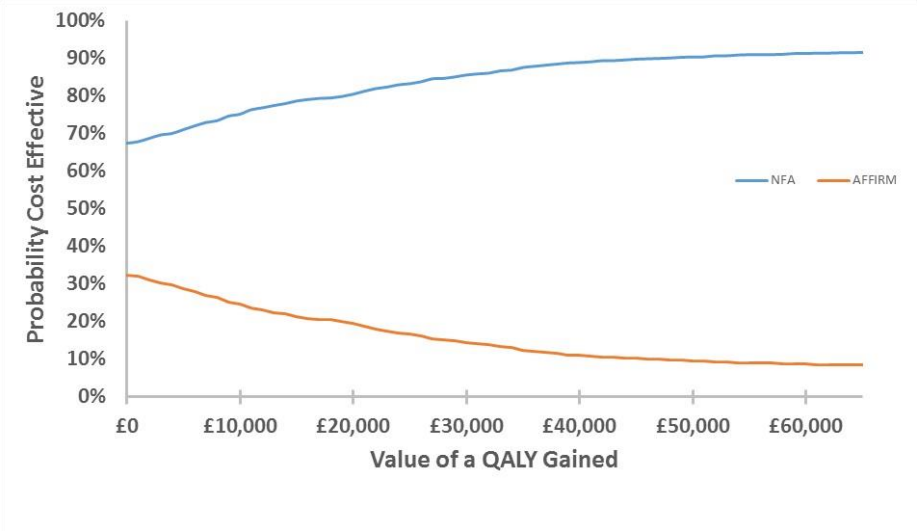


Figure 5: Cost effectiveness plane: No formal awareness package (NFA) versus Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): perinatal mortality



1.4.2 Mindfetalness versus No formal awareness package (NFA)

Table22 shows the deterministic results for Mindfetalness compared with NFA and Table23 displays the probabilistic results. The ICER, whilst positive is slightly counterintuitive in that Mindfetalness is both less costly and less effective than NFA. At a threshold of £20,000 the iNMB is positive, indicating that Mindfetalness, when compared with NFA is not cost effective. Table23 shows the probabilistic results of the same analysis.

Table22: Deterministic results: Mindfetalness versus no formal awareness package (NFA)

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER**
Mindfetalness	£3,129		24.386		-
NFA	£3,146	£18	24.390	0.004	**£4,101**

ICER: Incremental Cost Effectiveness Ratio; NFA: No Formal Awareness Package; QALY: Quality-adjusted Life Years.

Table23: Probabilistic results: Mindfetalness versus no formal awareness package (NFA)

	Cost		QALYs		
Treatment Strategy	**Total**	**Incremental**	**Total**	**Incremental**	**ICER**
Mindfetalness	£3,006		24.386		-
NFA	£3,022	*£16*	24.391	*0.004*	**£3,691**

ICER: Incremental Cost Effectiveness Ratio; NFA: No Formal Awareness Package; QALY: Quality-adjusted Life Years.

Table24: Mean incremental net monetary benefit and the probability of cost effectiveness

Pairwise comparison	Mean iNMB (threshold=£20K)	Probability NFA is cost effective (n=1000)
PSA3: Mindfetalness versus NFA	-£72	74%

iNMB: Incremental Net Monetary Benefit, NFA: No Formal Awareness Package, PSA: Probabilistic Sensitivity Analysis.

1.4.2 Three-way analysis

Table 25 shows the results of the three-way analysis with results from Norman 2018 used as the baseline values. NFA has the highest incremental Net monetary benefit and the greatest number of QALYs suggesting it is the preferred option when a £20,000 per QALY threshold is assumed. Mindfetalness is the least costly but only saves £3 per pregnancy compared to NFA. An ICER for Mindfetalness against NFA in this analysis would be £250 per QALY significantly below a threshold of £20,000 per QALY.

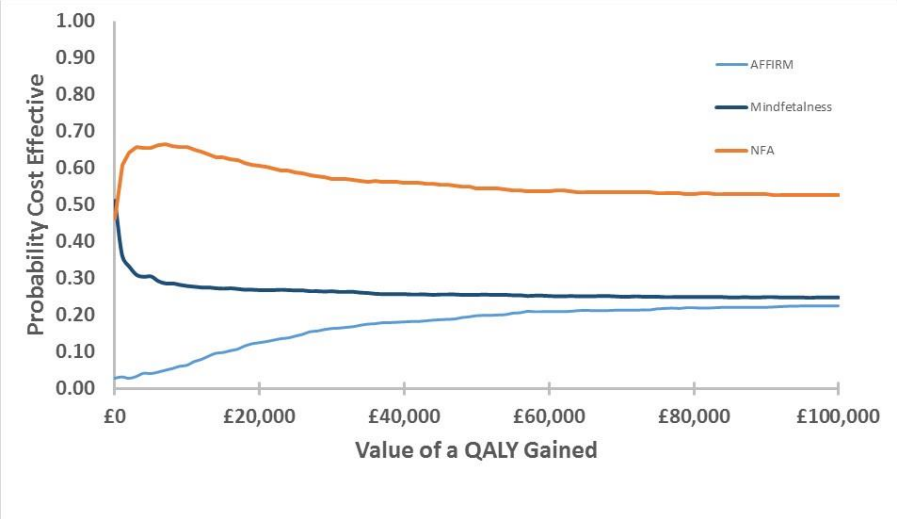
Table25: Deterministic three-way analysis

	Cost		QALYs			iNMB
Treatment Strategy	Total	Incremental	Total	Incremental	ICER	
AFFIRM	£3,593		24.283		-	-
Mindfetalness	£3,408	*-£185*	24.279	*-0.00*	£45,156	£103
NFA	£3,411	*-£182*	24.290	*0.006*	**Dominant**	£305

iNMB: Incremental Net Monetary Benefit, NFA: No Formal Awareness Package

Figure 6 shows the CEAC for the three-way analysis. In this analysis NFA stay above 50% for all thresholds up to £100,000 per QALY. AFFIRM approaches Mindfetalness as the threshold increases but never has a higher probability of being cost effective than either NFA or Mindfetalness for thresholds less than £100,000 per QALY. AT a threshold of £20,000 per QALY AFFIRM, Mindfetalness and NFA have a 12%, 27% and 61% probability of being the preferred approach.

Figure 6: Cost effectiveness plane: Three-way analysis no formal awareness package (NFA) versus AFFIRM versus Mindfetalness



1.5 Discussion

The economic analysis conducted for this evidence review assesses the cost effectiveness of no formal awareness fetal movements package (NFA) with structured fetal movement awareness packages such as AFFIRM and Mindfetalness

The base case analysis considered NFA versus AFFIRM. In both the deterministic and probabilistic analysis, NFA was the dominant option. That is, NFA was associated with fewer costs and higher QALYs. This interpretation also holds when the model was run with one of the outcomes set to stillbirth in place of perinatal mortality. Given that the PSA around both assumptions indicated that NFA had a 82% probability of being the cost effective approach, the results lend credence for not making strong recommendations for formal awareness packages.

It is necessary to interpret these results alongside the Saving Babies' Lives report by NHS England (2016), encouraging maternal awareness of changes in fetal movements. The Norman study represents the best available evidence relevant to UK practice and included more than 400000 pregnancies at 33 UK hospitals. The report itself stated that they were awaiting the results of the AFFIRM trial as it would "give us the best evidence yet". Given that these the clinical outcomes of the base case analysis are solely based on Norman 2018, the results of this analysis are directly applicable to this wider decision making context.

The outcomes 'perinatal mortality' and 'stillbirth' are both not statistically significant in either of the studies identified for this economic analysis. Given the low base rates of these outcomes too, it is not surprising that these values were not a driver of cost effectiveness. The series of one-way sensitivity analysis indicated that the model results were robust at most extremes of individual parameter values, holding all else constant. The exception to this is elective and emergency caesarean section though it should also be noted that the extreme values that informed these estimates were not statistically significant and thus the relationship between awareness packages and changes in mode of deliveries are not certain.

In addition to the inherent statistical uncertainty of the AFFIRM effectiveness estimates, there is also considerable uncertainty over the structural assumptions of this analysis. Resource use data was not identified for all approaches considered, other than that Norman 2018 would broadly follow the management strategy outlined by the RCOG Green Top guideline 57. However, differing estimates of resource use are likely to exist between the two strategies, even if the difference is nuanced.

Norman 2018 did not report the relative differences in contact with healthcare services between the two approaches, though the committee were unanimous that there would be an increase in ultrasound scans and unscheduled maternity visits owing to increased awareness of reduced fetal movements. In order to capture this effect in the base case analysis, the model included data from the SBL report which showed a 24% relative increase in ultrasound scans. This estimate is quite unreliable as it is based on before/after data and concerns all elements of the care bundle. Nevertheless, two-way sensitivity analysis demonstrated that NFA is cost effective when compared with AFFIRM at all assumptions. This includes extreme assumptions such as a woman undergoing 5 scans in NFA compared with 1 scan in AFFIRM.

Another source of uncertainty was the estimated utility value of maternal anxiety. In order to reflect the protocol of this evidence review, an assumption was made that a proportion of women who undergo AFFIRM would experience a decrement on the anxiety domain of the EQ-5D. However, the results of the one-way sensitivity analyses and scenario analysis indicate that NFA was still dominant.

The analysis considered a broad range of clinical outcomes relevant to mothers and babies. However, other relevant outcomes that relate to morbidity that may alter the interpretation of cost effectiveness were not possible to consider in the economic model. This was due to either due to a lack of suitable and/or good quality epidemiological and economic data that would allow for robust modelling to be conducted, or due to the uncertainty of modelling owing to multifactorial cause of certain contraindications. For example, admission to NICU may be associated lifetime morbidities for the fetus which are not captured in the model. When considered over a lifetime horizon, the associated costs and disabilities may be considerable.

Moreover, the estimated ICER only captures benefits expressed in the form of QALYs. Whilst this best reflects the NICE Reference Case to inform allocation of scarce resources, the model doesn't fully reflect all the incremental differences in effects for all outcomes owing to a lack of published data. For example, through elicitation maternal utilities for a range of adverse birth outcomes such as admission to NICU.

Mindfetalness was compared to NFA as a separate analysis as NFA best reflected 'standard care' as described in Akselsson 2020. It is important to note that Mindfetalness differs from AFFIRM in that the intervention is aimed solely at women, rather than healthcare professionals as well. The study demonstrated that patients who underwent Mindfetalness were less likely to experience an expedited birth and had a higher chance of attending a maternity unit owing to RFM. The outcomes on stillbirth and perinatal mortality were insignificant. The probability of Mindfetalness being cost effective was 36% in a PSA. However, there is considerable uncertainty around the incremental QALY gain. In comparison to the Norman paper, there may be systematic differences in Swedish maternal healthcare provision that makes the study less applicable than that of Norman 2018.

All three potential approaches were also compared against each other. Given the differences in populations and antenatal care this should be interpreted with caution. However, this analysis did lend further wait to the conclusion that formal awareness packages may not be an efficient use of NHS resources.

1.6 Conclusion

The economic analysis conducted for this evidence review suggests that structured fetal movement awareness packages are unlikely to be cost effective from a UK NHS & PSS perspective.

1.7 References

Akselsson 2020

Akselsson, A., Lindgren, H., Georgsson, S., Pettersson, K., Steineck, G., Skokic, V., & Rådestad, I. Mindfetalness to increase women's awareness of fetal movements and pregnancy outcomes: a cluster-randomised controlled trial including 39 865 women. BJOG, 127, 829-837, 2020

Alfirevic 2016

Alfirevic, Z., Keeney, E., Dowswell, T., Welton, N. J., Medley, N., Dias, S., ... & Caldwell, D. M. Which method is best for the induction of labour?: A systematic review, network meta-analysis and cost-effectiveness analysis. Health technology assessment, 2016

Campbell 2018

Campbell, H. E., Kurinczuk, J. J., Heazell, A. E. P., Leal, J., & Rivero-Arias, O. Healthcare and wider societal implications of stillbirth: a population-based cost-of-illness study. BJOG: An International Journal of Obstetrics & Gynaecology, 125, 108-117, 2018

Curtis and Burns 2019

Curtis, L., & Burns, A. Personal social services research unit university of kent. Unit Costs of Health and Social Care, 2019

Draper 2019

Draper, E. S., Gallimore, I. D., Kurinczuk, J. J., Smith, P. W., Boby, T., Smith, L. K., & Manktelow, B. N. (2019). MBRRACE-UK perinatal mortality surveillance report, UK perinatal deaths for births from January to December 2017. Leicester: The infant mortality and morbidity studies, department of health sciences, University of Leicester. Available from: https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK%20Perinatal%20Mortality%20Surveillance%20Report%20for%20Births%20in%202017%20-%20FINAL%20Revised.pdf [Accessed 07/03/2020]

Kind 1999

Kind, P., Hardman, G., Macran, S. UK Population norms for EQ-5D. Discussion paper 172. York: Centre for Health Economics, The University of York, 1999

Green-top guideline 57 2016

Green-top guideline No, R. C. O. G. (2016). 57: reduced fetal movements. London: Royal College of Obstetricians and Gynaecologists; 2011.

National Schedule of NHS Costs 2018

NHS Improvement (2019) National Schedule of Reference Costs. Year 2018-19 - NHS trusts and NHS foundation trusts. Available from: https://improvement.nhs.uk/resources/national-cost-collection/[Accessed 19 March 2020]

NHS: Saving Babies' Lives Care Bundle 2016

England, N. H. S. (2016). Saving Babies' Lives-A care bundle for reducing stillbirth. London: NHS England, 30. Available from: https://www.england.nhs.uk/wp-content/uploads/2016/03/saving-babies-lives-car-bundl.pdf [Accessed 4th March 2020]

NICE Guideline Manual 2014

National Institute for Health and Care Excellence (2014) Developing NICE guidelines: the manual. 2018. (PMG20). Available from: https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview [Accessed 19 April 2020]

NICE Surveillance Report 2017

National Institute of Health and Care Excellence (2017). Surveillance report. Antenatal care for uncomplicated pregnancies (2008) NICE guideline CG62. Available from: https://www.nice.org.uk/guidance/cg62/resources/surveillance-report-exceptional-review-2017-antenatal-care-for-uncomplicated-pregnancies-2008-nice-guideline-cg62-pdf-5642407886533 [Accessed 5/02/2020]

Norman 2018

Norman, JE., Heazell, AEP., Rodriguez, A., Weir, CJ., Stock, SJE., Calderwood, CJ., Cunningham Burley, S., Frøen, JF., Geary, M., Breathnach, F., Hunter, A., McAuliffe, FM., Higgins, MF., Murdoch, E., Ross-Davie, M., Scott, J., Whyte, S., AFFIRM investigators. Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial, Lancet, 392,1629-1638, 2018

ONS 2018

Office for National Statistics (2018). Birth Characteristics in England and Wales, 2018. Available from https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthcharacteristicsinenglandandwales [Accessed 18/03/0202]

ONS 2019

Office for National Statistics (2019). National Life Tables, England, 2016-2018. Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesunitedkingdomreferencetables [Accessed 03/03/2020]

Petrou 2017

Petrou, S., Kim, S. W., McParland, P., & Boyle, E. M. Mode of delivery and long-term health-related quality-of-life outcomes: a prospective population-based study. Birth, 44, 110-119, 2017

Szende 2007

Szende, A. G. O. T. A. EQ-5D value sets: inventory, comparative review and user guide. M. Oppe, & N. J. Devlin (Eds.). Berlin, Germany: Springer, 2007

Wastlund 2019

Wastlund, D., Moraitis, A. A., Thornton, J. G., Sanders, J., White, I. R., Brocklehurst, P., ... & Wilson, E. C. The cost-effectiveness of universal late-pregnancy screening for macrosomia in nulliparous women: a decision analysis. BJOG: An International Journal of Obstetrics & Gynaecology, 126, 1243-1250, 2019

Widdows 2018

Widdows, K., Roberts, S., Camacho, E., & Heazell, A. (2018). Evaluation of the implementation of the Saving Babies' Lives Care Bundle in early adopter NHS Trusts in England. Manchester, UK.

Appendix K – Excluded studies

Excluded studies for review question: Is fetal movement monitoring from 28 weeks effective?

Clinical studies

Table26: Excluded studies and reasons for their exclusion

Study	Reason for exclusion
Bellussi, F., Po, G., Livi, A., Saccone, G., De Vivo, V., Oliver, E. A., Berghella, V., Fetal Movement Counting and Perinatal Mortality: A Systematic Review and Meta-analysis, Obstetrics and Gynecology, 135, 453-462, 2020	References checked and no relevant references matching PICO
Delaram, M., Poor, F. S., Jafarzadeh, L., Effects of fetal movement counting on mental health of mother in third trimester: A randomized controlled trial, Iranian journal of obstetrics, gynecology and infertility, 18, 8-14, 2015	Full text unavailable
Delaram, M., Shams, S., The effect of foetal movement counting on maternal anxiety: A randomised, controlled trial, Journal of Obstetrics & GynaecologyJ Obstet Gynaecol, 36, 39-43, 2016	Study conducted in Iran
Flenady, V., Gardener, G., Boyle, F. M., Callander, E., Coory, M., East, C., Ellwood, D., Gordon, A., Groom, K. M., Middleton, P. F., et al.,, My Baby's Movements: a stepped wedge cluster randomised controlled trial to raise maternal awareness of fetal movements during pregnancy study protocol, BMC pregnancy and childbirth, 19, 430, 2019	Clinical trial entry. Only protocol available, full results not yet published.
Kafali, H., Derbent, A., Keskin, E., Simavli, S., Gozdemir, E., Effect of maternal anxiety and music on fetal movements and fetal heart rate patterns, Journal of maternal-fetal & neonatal medicine, 24, 461-4, 2011	Study does not focus on whether fetal movement monitoring from 28 weeks is effective
Kamalifard, M., Abbasalizadeh, S., Ghojazadeh, M., Ghatreh Samani, F., Rabiei, L., Diagnostic value of fetal movement counting by mother and the optimal recording duration, Journal of Caring SciencesJ Caring Sci, 2, 89-95, 2013	This study is not a randomised controlled trial
Lalor, J. G., Fawole, B., Alfirevic, Z., Devane, D., Biophysical profile for fetal assessment in high risk pregnancies, Cochrane Database of Systematic Reviews, CD000038, 2008	The population in this study focuses on high-risk pregnant women
Linde, A., Georgsson, S., Pettersson, K., Holmstrom, S., Norberg, E., Radestad, I., Fetal movement in late pregnancy - a content analysis of women's experiences of how their unborn baby moved less or differently, BMC Pregnancy & ChildbirthBMC Pregnancy Childbirth, 16, 127, 2016	This study is not a randomised controlled trial
Malm, M. C., Radestad, I., Rubertsson, C., Hildingsson, I., Lindgren, H., Women's experiences of two different self-assessment	This study is not a randomised controlled trial

Study	Reason for exclusion
methods for monitoring fetal movements in full-term pregnancy--a crossover trial, BMC Pregnancy & ChildbirthBMC Pregnancy Childbirth, 14, 349, 2014	
Mangesi, L., Hofmeyr, G. J., Smith, V., Smyth, R. M. D., Fetal movement counting for assessment of fetal wellbeing, Cochrane Database of Systematic Reviews, 2015	This is a relevant Cochrane review. All the relevant studies have been extracted and added to this review
Michaan, N., Baruch, Y., Topilsky, M., Amzalag, S., Iaskov, I., Many, A., Maslovitz, S., The effect of glucose administration on perceived fetal movements in women with decreased fetal movement, a double-blinded placebo-controlled trial, Journal of perinatology : official journal of the California Perinatal Association, 36, 598-600, 2016	Study does not focus on whether fetal movement monitoring from 28 weeks is effective
Mikhail, M. S., Freda, M. C., Merkatz, R. B., Polizzotto, R., Mazloom, E., Merkatz, I. R., The effect of fetal movement counting on maternal attachment to fetus, American Journal of Obstetrics and Gynecology, 165, 988-91, 1991	Maternal-attachment outcome only, not specified in the protocol
Nct,, Analysis of the Use of the Fetal Movement Counting for Prolonged Pregnancy, https://clinicaltrials.gov/show/NCT04117308, 2019	Clinical trial entry. Trial includes a subpopulation of women. Protocol specifies unselected women.
Porreco, Richard P., Bellussi, Federica, Livi, Alessandra, Po, Gaia, Fetal Movement Counting and Perinatal Mortality: A Systematic Review and Meta-analysis, Obstetrics & Gynecology, 135, 1227-1227, 2020	Systematic review matching PICO. References checked and relevant references have already been included.
Thomsen, S. G., Legarth, J., Weber, T., Kristensen, J., Monitoring of normal pregnancies by daily fetal movement registration or hormone assessment. A random allocation study, Journal of obstetrics and gynaecology, 10, 189-93, 1990	Comparator is hormone assay, not specified in the protocol
Saastad, E., Israel, P., Ahlborg, T., Gunnes, N., Froen, J. F., Fetal movement counting--effects on maternal-fetal attachment: a multicenter randomized controlled trial, Birth (Berkeley, Calif.), 38, 282-293, 2011	Maternal-attachment outcome only, not specified in the protocol

Economic studies

A single economic search was undertaken for all topics included in the scope of this guideline. No economic studies were identified which were applicable to this review question. See supplementary material 2 for details.

Appendix L – Research recommendations

Research recommendations for review question: Is fetal movement monitoring from 28 weeks effective?

No research recommendations were made for this review question.